

## A Quality Management Perspective

### Introduction

The goal of quality management at Los Alamos is to make science less expensive and more efficient to produce. By the use of a management model that addresses the activities that support science, many Los Alamos managers have been able to realize an implemented, science supporting, management system. The next few pages present such a system, then discuss a step-by-step method for achieving the quality management goal. The tabbed section includes the details of implementation guidance, and some worksheets. By the time managers complete the worksheets, they will have completed an assessment of their existing quality documents. Most managers are surprised to realize they may take credit for existing documents as they apply quality requirements without changes. After completing the worksheets, they also will have a quality development plan, an approved schedule, and be ready to begin the implementation of a quality management system.

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### Science and Quality Management

Scientific advancement results from the rigorous application of the scientific method: observation, formulation of a hypothesis about the observation, development of a method to test the hypothesis, test of the hypothesis, and documentation of both method and results. Without documentation of the results, the knowledge gained would be lost; without documentation of the method, the results might be readily contradicted by those who document a method and reach different results. Documentation of method as well as results allows re-examination and revalidation by those who wish to follow the original process to again test the outcome.

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### Steps of Quality Management

Because the scientific method incorporates such a means for achieving quality management (QM), programs to provide QM are appropriate complements to the Laboratory's programs of scientific research and development. Like the scientific method, the QM method comprises certain basic steps:

- Plan what you do.
- Do what you plan.
- Document what you do.
- Assess the results.
- Improve the process.

These steps are all essential to the good management and effective conduct of operations, processes, and activities in business, industry, and science. Good management as well as good science is needed so that we can continue to do what we have done well for over 50 years. Well-designed and readily adaptable QM programs provide us with the tools to ensure that the Laboratory can compete with other institutions for the scientific programs that attract research dollars. QM principles are applicable both to scientific programs and to the wide range of activities that indirectly support those programs.

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### Applying the Customer/supplier model

Quality is synonymous with excellence and superiority—both acknowledged worldwide as characteristics of the science conducted here at the Laboratory. A high level of quality in a supplier/customer environment is defined as the extent to which a product or service provided by the supplier satisfies the customer. In the past, this marketplace definition did not seem to apply directly to our work here at the Laboratory. We were secure in our mission as a prime provider of the nuclear technology that served as the cornerstone of national security. Today there is much more public awareness of Laboratory activities and this means we need to publicly satisfy our customer.

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### QM helping science

But the past several years have brought global changes whose results have been redefinition of the national security concept to include economic interests and greater attention to environmental and other public issues. For these reasons, quality performance in scientific research and development alone will no longer ensure that funding for the Laboratory—and, therefore, research and development activities—will continue at previous levels. Quality must pervade all aspects of every activity in which we are engaged, not only in our conduct of science but also in our interactions with other institutions, with various government agencies, with private industry. In short, it must be obvious to all those who are or are likely to become customers for the products and services we are uniquely qualified to supply.

The QM program at the Laboratory seeks to optimize the existing tradition of excellence and superiority in science. The program offers a structured approach to self-evaluation and self-improvement. Line managers can use this approach to optimize the conduct of their programs and projects.

## The Laboratory Perspective

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### Definitions of Quality

The QM program envisioned for the Laboratory is founded on definitions formulated by the American National Standards Institute and the Institute for Electrical and Electronic Engineers and by the Department of Energy (DOE). According to ANSI/IEEE STD 730-1984, Quality Assurance, now becoming synonymous with Quality Management, is "a planned and systematic pattern of all actions necessary to provide adequate confidence that the item or product conforms to established technical requirements". The DOE definition is similarly action oriented: Quality Assurance/Quality Management comprises "all those actions that provide confidence that quality is achieved".

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### QM process

QM at the Laboratory is defined to embrace the concept of continuous quality improvement. QM is a process in which management tools, systematically developed and implemented by the management and staff of an organization are implemented to produce and continually improve its products. The result of implementing a QM program gives confidence that those products at least meet the customer's operational, functional, and technical requirements and expectations. Briefly, QM comprises all of the planned and systematic actions necessary to provide adequate confidence that a facility, structure, system, component, or process will perform satisfactorily in service.

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### QM an improvement process

QM is a continuing process. The line manager who, with the help of other personnel in the organization, develops and implements a QM program seeks thereby to produce a system of useful management tools that aid the organization in doing its work. If the QM program fails to accomplish this goal, then the plan must be improved and it becomes the subject of one of the quality criteria—criterion 3; quality improvement.

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### LANL customer

The planning and implementation of any QM program will consider the wants and needs of its customers—both internal and external. As our primary external customer, the Department of Energy (DOE) plays a major role in the way we approach most of the activities we conduct—and QM is no exception.

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### Legal implications

**We at the Laboratory must understand the legal implications of and respond to the rules and regulations Code of Federal Regulations 10 CFR 830, *Nuclear Safety Management*. We must plan, develop, document, and implement, using a graded approach, QM programs in virtually all of our activities. Specifically, 10 CFR 830.120 contains the Quality Assurance Requirements for nuclear facilities. It will be referred to as "the Rule" or "The CFR Rule". As long as DOE Order 5700.6C is still in effect it is mandatory for non-nuclear facilities. It will be referred to as "the Order".**

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### Guidebook structure

The structure of this Guidebook derives from the structure of the DOE Order on Quality Assurance, 5700.6C, a series of 10 QM criteria. Its substance reflects the substance of the Rule and its supplemental guidance, Safety Guide SG 830.120, "Guidelines for Developing and Implementing Quality Assurance Programs."

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### QM assistance

Although use of the Guidebook is not mandatory, it does facilitate understanding of the Rule's requirements, which are mandatory for nuclear facilities. In addition, the Quality Management Support Group approves the statements of applicability and implementation status provided for on forms placed within each of the 10 tabbed sections in the Guidebook and provides assistance to organizations seeking to identify applicable QM requirements.

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## The Guidebook Approach

### Beginning a QM program

If you have not already developed a QM program, then beginning the development of a QM plan and its implementing procedures should consist primarily of preparing a documented description of your activities and how they are conducted. The analysis you do as you prepare these materials may identify some deficiencies and suggest opportunities for improvement. So the process of developing a QM plan for a technical program that is in progress may stimulate assessment of work being performed.

<b>Coordinating QM</b>	<p>For new projects, the development of the QM plan and procedures should be coordinated closely with the program planning process to ensure that the QM effort is, indeed, a benefit to the overall effort. Development begins with the identification and definition of the primary goals and supporting activities of the technical effort while considering the hazards and risks involved. Next, using what is now known about the program or project, determine the applicability of the QM criteria in the Rule.</p>
<b>Evaluating organization status</b>	<p>For those criteria that have been determined as applicable, evaluation of organization management status is done by reviewing the following:</p> <ul style="list-style-type: none"> <li>• existing activities and substantiating documentation;</li> <li>• the Code of Federal Regulations Rule, 10 CFR 830.120 (QM Reference 2, and Department of Energy Order, DOE Order 5700.6C (QM Reference 3, part 1);</li> <li>• the Safety Guide for 5700.6C (QM Reference 3, part 2);</li> <li>• the Codes and Standards Applicable to Quality Assurance and Quality Management (QM Reference 6); and</li> <li>• the appropriate tabbed sections in this Guidebook.</li> </ul> <p>Having completed a review of the above documents, a comparison with the Rule or Order requirements and the LANL response lets a manager evaluate the organization's status. With this evaluation the worksheets may be completed for each criterion. The worksheets are at the end of each tabbed section (criterion).</p>
<b>Determine QM documentation for activities</b>	<p>For QM-related activities not covered by existing documentation, determine which type of document—such as a procedure, a work process description, an organizational chart, or a responsibility matrix—best suits the need and develop the needed QM documentation that will complete the QM program. Finally, implement the program by following through with the QM plan and implementing procedures and other documentation. By recognizing common pitfalls of QM programs, strategies can be developed for QM program planning and implementation. The Quality Management Support Group has staff available to help managers through program development.</p>
<b>Developing QM procedures</b>	<p>The QM plan and procedures should describe what you actually do or intend to do. QM plans and procedures may be construed as promises. Avoid the danger of making promises you cannot keep, i.e., develop real and accurate procedures (what you actually do), rather than hypothetical, or ideal, procedures (what you wish you were doing or what you think someone else thinks you should be doing).</p>
<b>Apply graded approach to QM</b>	<p>The application of a "graded approach" to QM is somewhat different from the original interpretation of the term that was a categorization based on technical safety appraisals. Such an application is appropriate for projects involving nuclear facilities. However, in complying with the Rule or DOE Order 5700.6C, a somewhat different interpretation applies in most Laboratory programs and organizations. The QM view provides that requirements be implemented at the level needed. Thus, the quality level of a given program may be defined by selective and judicious application of DOE order requirements commensurate with the level of detail required for activities based on such factors as environment, safety, and health, complexity, and programmatic risks. QM program planners are, therefore, advised to apply requirements in a sensible manner. The definition of "graded approach" in the Rule is strongly supported by this as one can see from its definition:</p>
<b>Graded Approach</b>	<p>"Graded Approach means a process by which the level of analysis, documentation, and actions necessary to comply with a requirement in this Part are commensurate with:</p> <ol style="list-style-type: none"> <li>(1) The relative importance to safety, safeguards, and security;</li> <li>(2) The magnitude of any hazard involved;</li> <li>(3) The life cycle stage of a facility;</li> <li>(4) The programmatic mission of a facility;</li> <li>(5) The particular characteristics of a facility; and</li> <li>(6) Any other relevant factor."</li> </ol>

## Quality at LANL

The goal of this Guidebook is to provide you with a method of improving the way your organization satisfies its customers. The Guidebook seeks to promote quality at the Laboratory by:

- responding to both 10 CFR 830.120, Nuclear Safety Management Quality Assurance Requirements, and DOE Order 5700.6C, Quality Assurance, and following the LANL Quality Assurance Management Plan (PRD110-01.0), since both have very similar requirements. The major differences are in criteria one and nine. For criterion one, Program, the requirements of the Order apply to organizations, and for the Rule they apply to facilities. Criterion nine in the Order is an assessment of the Quality Assurance Program, but in the Rule it is an assessment of Management Processes;
  - introducing you to the basic principles of QM that you may integrate into your own day-to-day activities;
  - encouraging creativity in QM planning by providing non-prescriptive guidance;
  - providing you with enough detail to get started but not so much that you are immobilized by the prospect;
  - referring you to appropriate sources, such as the Quality Management Reference Manual, when more details are needed; and
  - providing guidance in the writing of the QM plans and procedures and the implementation of the developed QM program.
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## Guidebook worksheets

If all criteria of the Rule or the Order, apply, then your QM plan will have 10 sections, one responding to each criterion, and a short description of each implementing procedure, at least one for each element. Some criteria may require more than one procedure. Each of the 10 separately tabbed and numbered sections in this Guidebook corresponds to a DOE criterion and includes DOE guidance supplemented by brief tips for addressing program implementation. A single form, consisting of three parts, accompanies each criterion and is intended to guide the development of the individual QM program. Remember that you do not need to duplicate earlier efforts simply to demonstrate program implementation:

**Cross-references to existing documents are sufficient. Develop new documentation only for those areas in which no documentation or inadequate documentation exists.**

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## Other requirements

Although the content of this Guidebook is organized to ensure that Laboratory programs, projects, and organizations address the 10 criteria specified in the Rule or the Order, some programs and projects must address other QM regulatory, statutory, and work process requirements (such as those specified by their customers). The *Quality Management Reference Manual* contains references to other QM requirements some individual programs and projects at the Laboratory are already addressing.

**Well-planned existing QM programs whose formats differ substantially from the DOE criteria but which, nevertheless, satisfy all of its requirements may need only appropriate documentation, such as a cross-referencing guide, to demonstrate that the program responds to the provisions of the DOE order.**

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## Fermi Laboratory's DOE Order matrix

Fermi Laboratory developed a matrix to demonstrate the correlation between DOE Order 5700.6C, the DOE Order on which the Rule is based, and the ASME standard for the nuclear power industry, NQA-1. The matrix lists the 10 criteria of the DOE order horizontally as column headings and the 18 elements of NQA-1 vertically as row headings. Check marks or dots are placed in intersection boxes to designate common requirements. Thus, the matrix demonstrates, for example, that Criterion 6, "Design Control," of the order corresponds to element 3, also "Design Control," of the standard. Such matrices can be developed for any two similar documents. Differences, identified when one-to-one correlations cannot be designated, are accommodated for separately addressing non correlating provisions.

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**No "cookbook" QM**

The optimum goal of all QM programs is the same—use a systematic approach from a project's inception to assure completion, on time, and within budget. Ideally, perhaps, we might develop a QM "cookbook" in which a manager might be able simply to replace a generic program name with the name of a particular program. Contributors to this Guidebook from throughout the Laboratory agreed that such a cookbook approach would detract from necessary planning of program management strategy, would be likely to impair the ability of programs to implement QM, and would probably result in harsh external assessments. Laboratory programs differ from each other in important ways, and their managers must, therefore, approach QM in different ways.

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**Likelihood of standardization**

However, some degree of standardization is likely to occur because programs share some of the same drivers: the structure of the relevant DOE order; the specific DOE guidance available; the use of standard Laboratory forms; common interaction with other Laboratory organizations; and the completion of forms provided in this Guidebook. Standard Laboratory forms include purchase requests. Interacting Laboratory organizations include: the Laboratory's Training and Development Office for course development guidance and the Facilities, Security, and Safeguards Division for design standards

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## A Related, but Separate, Concern: Quality Control

**Quality Control (QC)**

Whereas QM is largely a programmatic concern, quality control (QC) is a technical concern. QC is a process for measuring the actual quality performance of a product against an applicable standard or client specifications. Thus, the reliability of a scientific apparatus—that is, its ability to provide data whose quality is sufficient to meet program goals—is a concern that falls within the scope of QC.

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**The technical nature of QC**

Reference materials in QC differ significantly from reference materials in QM. For example, <sup>1</sup>*Quality Assurance in Research and Development* is a manual for managers and can be readily understood by technical and nontechnical staff alike, but <sup>2</sup>*Practical Reliability Engineering* requires that its reader possess a technical background. This highly technical manual for QC engineers assumes an understanding of differential equations and statistics. Such QC books are filled with mathematical formulas; discussions of statistical process control and acceptance test sampling. Various statistical distribution function curves (normal, binomial, and Poisson); and Pareto, Ishikawa, and Fishbone charts are also tools the QC engineer uses for work process control and decision making.

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**Laboratory QC Support**

Although QC is beyond the scope of this Guidebook and the Quality Management Support Group, managers of technical programs may need QC assistance. We refer you to the Technology and Safety Assessment Division, in particular group TSA-1, which has provided support in statistical QC, including both reliability physics and engineering, for over 25 years.

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## The Role of the Quality Management Support Group

**Help from the Quality Management Support Group**

The Quality Management Support Group (ESH-14) serves as the office of primary responsibility for QM throughout the Laboratory. It offers the expertise to assist Laboratory managers in developing, implementing, and assessing their own QM programs, and has coordinated the preparation of this QM Guidebook. Please feel free to call the Quality Management Support Group at (505) 665-5437 for specific guidance as needed.

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<sup>1</sup> *Quality Assurance in Research and Development*, by George W. Roberts

<sup>2</sup> *Practical Reliability Engineering*, by Patrick D. T. O'Connor, John Wiley & Sons, 1985.

## Summary Steps for Developing a QM Program

<b>Step 1</b>	<p>Identify and define the primary goals and supporting activities of your technical effort while considering the hazards and risks involved.</p> <p>The discussion you generate and the materials you assemble during this stage of program development will set the direction for fulfilling the requirements of the Rule (QM Reference 2, includes Safety Guide), and the Order [QM Reference 3, includes Implementation Guide]. They will form the basis for generating documentation for Criterion 1, Program, and will be integral to responses to other criteria. You should be able to identify the mission of your program, project, or organization; define the organization and its structure; and identify technical and nontechnical requirements.</p> <hr/>
<b>Considerations for defining project activities</b>	<p>As you specify your present project activities, consider the following:</p> <ul style="list-style-type: none"><li>• Does it create a management system with an effective infrastructure?</li><li>• Is the program at the conceptual stage? If so, it's a great time to start long-range QM planning.</li><li>• Is the program at the initial work stage? If so and if facilities engineering is needed, is another QM program involved?</li><li>• Is construction of scientific apparatus needed?</li><li>• Is any software needed? If so, is it being developed?</li><li>• What are your future program activities?</li><li>• Will the QM program be able to evolve as the program evolves?</li><li>• If you are a Laboratory support organization, who are your customers?</li><li>• Are you considering the "Customer/Supplier Model" being promoted by the DOE?</li></ul> <hr/>
<b>Critical issues</b>	<p>Be sure to identify the critical issues or processes for the program:</p> <ul style="list-style-type: none"><li>• What are the "show stoppers"?</li><li>• Are they regulatory, institutional, or operational?</li></ul> <hr/>
<b>Developments from Technical program</b>	<p>Once you've characterized your program, you will be able to decide where your program is going by answering two additional questions:</p> <ul style="list-style-type: none"><li>• What is your vision of your program?</li><li>• What logical developments may result from your program?</li></ul> <hr/>
<b>Beginning quality improvement</b>	<p>The answers to these two questions provide a starting point for quality improvement—so much the better if you can reach those answers before your program is in full operation. The information you develop in this step is for your own use in tailoring the QM plan to the particular program or project; it may or may not become part of your final QM plan.</p> <hr/>
<b>Step 2</b>	<p>Using what you now know about your program or project, determine the applicability of the QM criteria in 10 CFR 830.120 (and DOE Order 5700.6C as applicable).</p>
<b>"Tip" sheets References to Deming and Juran</b>	<p>The tip sheets referred to later in conjunction with the "ten tabbed sections of the Guidebook" were developed using DOE's <i>Implementation Guide for use with 10 CFR Part 830.120, Quality Assurance</i>, G-830.120-REV.0, dated April 15, 1994. The "Tips" were developed specifically for Los Alamos National Laboratory, though they may apply to other DOE facilities that rely heavily on the insight of the most recognized leaders in the Quality movement, Dr. W. Edwards Deming, and Dr. Joseph M. Juran.</p> <hr/>

<b>Dr. W. Edwards Deming</b>	Dr. Deming (1900 - 1994) received his doctorate in physics from Yale University in 1928. During World War II he was involved in a concerted effort to improve quality in the war industry. He visited Japan in 1947 and is considered the person who was the catalyst for the Japanese quality movement. In 1980 he was featured in an NBC white paper "If Japan Can, Why Can't We." This stimulated a number of major American corporations in their quest for quality on into the 1990's. His book, <sup>3</sup> <i>Out of the Crisis</i> sent shock waves through American industry. It totally changed some of the major corporations of America.
<b>Dr. Joseph M. Juran</b>	Dr. Juran (1904 -) was trained as an engineer, and since 1924 has pursued a career in management. His book <sup>4</sup> <i>Quality Planning and Analysis</i> (with Dr. F. M. Gryna) provides the basis for an understanding of statistical concepts, quality management and quality control. In his book <i>Out of the Crisis</i> , Dr. Deming quotes Dr. Juran on topics such as quality improvement, and his interaction with the Japanese to teach them statistical methods applied to process control.
<b>Applying "Tips" to worksheets</b>	<p>For each criterion, review the tips in the ten tabbed sections of the Guidebook and complete the form found at the end of each section, "Applicability, Implementation Status, and Development Plan for 10 CFR 830.120". The tip sheets present the Laboratory's response to the 10 criteria (found in the Laboratory <i>Quality Management Plan</i>, LANL PRD110-01.0), implementation guidance from the DOE Safety Guide, and tips to assist you in determining whether a particular criterion applies to your program, evaluating your implementation status, and planning for complete program implementation.</p> <ul style="list-style-type: none"> <li>• If the criterion does apply, check the appropriate applicability, and complete Part 2, Implementation Status.</li> <li>• If the criterion does not apply, provide written justification in Part 1 for excluding it from your QM program.</li> <li>• Repeat this process for each criterion in each tabbed section.</li> </ul>
<b>Step 3</b>	<p>For those criteria you have determined as applicable, evaluate your implementation status by reviewing</p> <ul style="list-style-type: none"> <li>• existing activities and substantiating documentation;</li> <li>• 10 CFR 830.120 (and The DOE Order 5700.6C as applicable);</li> <li>• the DOE Implementation Guide (in QM Reference 2);</li> <li>• the Codes and Standards Applicable to Quality Assurance and Quality Management (QM Reference 6); and</li> <li>• the appropriate tabbed sections in this Guidebook.</li> </ul> <p>For those criteria you have indicated as applicable on the three-part form (one for each criterion), review the separately tabbed sections in this Guidebook. List those documents that reflect your existing program implementation with DOE QM requirements. Such documents may consist of, for example, standard or safe operating procedures (SOPs). Remember that the procedures required by a given QM program <b>need not</b> duplicate existing procedures or management systems. If existing written procedures satisfy requirements, they should be listed on the three-part form and appropriately referenced within the final QM program documentation.</p>
<b>QM Development Plan Approval</b>	Next, refer to the first form at the end of the first tabbed section, "Quality Management Development Plan Approval." Note that the signature block includes provision for a Quality Representative. For each organization or program, line management should designate a Quality Representative who will serve as a point of contact on QM issues.
<b>QM Support Group concurrence</b>	Forward copies of the completed forms to the Quality Management Support Group, MS P949, for review, determination of applicable quality levels, and concurrence. See also the discussion of quality levels in the second to last paragraph on page 3.

<sup>3</sup> *Out of the Crisis*, by W. Edwards Deming, MIT press, Cambridge, MA., 1982.

<sup>4</sup> *Quality Planning and Analysis*, by J. M. Juran and Frank M. Gryna, Jr., McGraw-Hill, 1980.

<b>Step 4</b>	For QM-related activities not covered by existing documentation, determine which type of document—such as a procedure, a work process description, an organizational chart, or a responsibility matrix—best suits the need. Then, develop the needed QM documentation that will complete your QM program.
<b>Writers Guides</b>	Several different writers guides have emerged for Laboratory documents that implement the Director's policies and those DOE orders to which they respond. The <i>Policy Documents Requirements</i> (QM Reference 7), formerly titled <i>Writer's Guide for ES&amp;H Documents</i> , is one and the <i>Writers Guide for the Nuclear Materials Technology Division</i> at TA-55 is another. Each writer's guide has its own approach but generally includes common essential elements to describe program documents, procedures, management processes, etc.
<b>Site-specific writer's guides</b>	Plans are underway to revise the writer's guide into a Laboratory standard. Site-specific and organization-specific policy-implementation documents and policy-implementation documents, such as handbooks and manuals, that do not conform to the types covered by the writer's guide are not required to conform to the standard formats presented in that guide. However, preparers of QM documentation should establish or adopt from appropriate sources sufficient written guidance to ensure that required documentation standards are met. If you are uncertain whether your QM documents have Laboratory-wide application and, therefore, should follow the writer's guide, contact The Quality Management Support Group, (505) 665-5437.
<b>Before writing procedures</b>	Written procedures enable employees to make the QM plan work and may reveal deficiencies in the plan. The plan indicates those parts of the process that require formal procedures and provides guidance and direction for the procedures. Before developing procedures, consider whether other Laboratory organizations may provide appropriate input to the QM issue in question. The Business Operations Division and the Training and Development Office, for instance, have considerable influence on how most Laboratory organizations function. The assistance of these and other Laboratory organizations may prove invaluable in the development of your QM procedures.
<b>Identify requirements</b>	Identify the requirements in DOE orders, commercial, industrial, or regulatory codes and standards, and, equally important, customer requirements that must be met. At the same time, consider any environmental, safety, and health requirements that may apply. As you determine which requirements do apply, make note of the ones that <b>do not</b> apply. This may save you time and effort later.
<b>Procedure formats, changes</b>	Following the writer's guide or some other written standard for documentation will help ensure that your documents are sufficiently comprehensive and meet Laboratory and DOE requirements. Early and on-going self-assessment of your QM program will alert you to incorrect or inadequate procedures. Change them to accurately describe the work being done.
<b>Step 5</b>	Implement the program by following through with the QM plan and implementing procedures and other documentation.
<b>Assumptions for QM implementation</b>	You have already developed a QM plan (or perhaps simply documented your existing QM practice) and have written needed procedures or other documents. Or you have cross referenced existing procedures that are realistic representations of practices and procedures in your group. Your procedures will demonstrate your organization's approach to quality in all of its operations and in response to 10 CFR 830.120 (or DOE Order 5700.6C as applicable).
<b>Action plans for QM implementation</b>	Correctly written procedures tell you what steps must be followed for the QM process to continue as you already have it in place or to begin as you now have it planned. Management's QM action plan, developed with worksheets (forms) from each criterion, will include the logical steps that will lead to complete implementation and a schedule for that criterion. You may have identified some procedures that should go into effect immediately, whereas others may need to be delayed or implemented in a sequential rather than a concurrent manner. Remember to document the reasons procedures do not take effect immediately.

**Validating QM procedures**

Validation is sometimes required before implementation to assure usefulness or effectiveness of procedures. So you may wish to issue some procedures, such as software QM procedures, for trial usage. This validation requires that the procedures be used as if they are fully implemented. Such a "reality test" may reveal inaccurate steps that can be corrected before the procedure causes problems or reveals its shortcomings during implementation. Planning and documenting the process you use to validate, to modify, and finally to implement procedures are also part of your QM effort.

Another form of procedure validation is to "walk through" the procedure. In other words observe the steps of the procedure as they are being implemented. This should reveal inconsistencies almost on a real time basis.

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**QM employee training**

In addition to participating in the Lab's General Employee Training (GET) program, each employee in your organization should receive orientation in the overall QM process as embodied in the plan. QM orientation for all employees should encompass the broad concepts on which the QM program is based—that is, it should cover the program's response to the DOE's 10 criteria but should not detail all of the supporting procedures. Each employee should also receive specific QM training that is consistent with program requirements for the particular work performed. QM training should emphasize each employee's personal responsibility in implementing an effective QM program.

Training on the support procedures should be given on an as-needed or "just in time" basis. For instance, all personnel should have a general idea that many activities described as work processes are part of the QM effort, but they do not need training on a specific QM procedure unless they must use that process in their work.

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**Assessing management, QM processes**

After a QM program has been initiated, even before it is fully implemented, you may want to assess its status. Criterion 9 describes self-assessment (or management assessment). Answering the question, "Are the management processes by which my program is controlled as effective as they should be?" may be a question new to many laboratory organizations. The answers may reveal how effective the organization really is. Remember, this assessment is not an assessment to tell you if you have good managers, though it may do that. It is an assessment to tell you whether or not your management processes are effective. Developing better managers who know how to implement management processes is accomplished through training managers to manage.

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**Appraisals by independent assessors**

You are ready for an independent assessment when you feel comfortable with the way this management tool is helping you run your program. This should be after your program is developed and implemented, and after management assessments have been made to ascertain its efficiency and effectiveness. Such an assessment is performed by auditors who do not have direct responsibilities for the work being assessed. They take an objective position at best, as they represent the interests of our clients. Their assessment carries the most weight with those who control program funding and who, in most cases, have a strong influence on program direction. Clients use the independent assessment to take a good look not only at your scientific and technical output but also at your management style. That is the effectiveness with which you can plan, develop, and implement the process that produced the output. Again, the Quality Management Support Group is a service organization that can help you prepare for, and even coach you through, an independent assessment.

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**Using assessment procedures**

You probably either already have a management assessment procedure that you have cross referenced or by now will have developed such a procedure. You may use it to conduct initial assessments of your program, to check the status of the program at points in time, and to check the efficacy of specific procedures. The distribution of a report that results from a self-assessment may be limited to internal recipients or may extend to external recipients at the discretion of line management.

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**QM Support Group assessments**

The Quality Management Support Group offers performance-based assessments that will tell you the good news as well as the bad news. Self-assessments, your own or those conducted by the Quality Management Support Group, give you the information you need to pursue the goal of continuous quality improvement. They also alert you to your program's strengths and weaknesses before an external assessment results in an adverse finding.

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## Assessments to improve

When your QM program has been developed, implemented, and independently assessed, you will be in an ideal position not only to improve your program but also to help others. To ensure that we take full advantage of “lessons learned,” please take the time to evaluate this Guidebook and any QM training you may have received from the Quality Management Support Group. Use the form at the front of this Guidebook to provide us with your feedback.

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## Step 6

Good strategies for developing a QM program:

- Include routine administrative procedures only if they are essential to your QM program.
  - Document plans only for those activities you intend to do, not for what you hope to do or ideally would like to do.
  - Include dates for document issue only.
  - Rely only on your organization to implement your QM program unless other organizations that share common activities have a QM program that uses the same QM standard that you use, or their procedures meet your QM requirements.
  - Implementation schedules for QM procedures should be left for a separate document.
  - Train personnel only on those QM procedures that directly involve them.
  - Prepare documents after you have established a consistent format.
  - Require procedural approval as close to work as possible.
  - Keep procedures as simple and succinct as possible without being so simple they leave out steps.
  - Give each procedure a trial run.
  - You may even want to use several related procedures in a trial implementation period to assure their effectiveness.
  - Develop program procedures only after you have formulated clear and accurate definitions of program processes.
  - Implement procedures only after you're sure they're safe and correct from the QM perspective.
  - Be flexible, QM programs are not "cast in concrete". They must be considered as "living" so program changes may be adopted as quickly and accurately as possible.
- 

## Step 7

Ask for help when you need it.

**CALL FOR HELP!** The Quality Management Support Group is here to provide support in developing and implementing individual QM plans and procedures. Although we cannot tell you how to run your program or solve your problems for you, we can coach you on the fundamentals of QM and suggest solutions to your QM problems. Our goal, as preparers of this Guidebook and as a service organization on call to programs throughout the Laboratory, is to see that you have formal processes and tools you need to customize your own QM program and operate it successfully. The Quality Management Support Group is **ESH-14**, Mail Stop, **P949**, and phone number **(505) 665-5437**.

## CRITERION 1 PROGRAM

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### Requirements for a QAP

Requirements from 10 CFR Part 830.120, (C), (1), (i), and DOE Order 5700.6C, criterion 1:

- {1} A written Quality Assurance Program (QAP) shall be developed, implemented, and maintained. (From DOE Order 5700.6C; Organizations shall develop, implement, and maintain a written Quality Assurance Program.)
  - {2} The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work.
  - {3} The QAP shall describe the management system, including planning, scheduling, and cost control considerations.
- 

### Criterion One LANL response

Response from the LANL Quality Assurance Management Plan (QAMP), page 3, section 4.1:

- Within the Laboratory, each organization's written QM program will encompass the key activities and management controls necessary to implement effective QM processes.
- Each organization must define, plan, and implement a management system that incorporates methods for managing, performing, assessing the work of the organization, and demonstrating that a system has been or will be implemented.
- This system should employ a graded approach to the work. (See the section on Graded Approach, page 3.)
- This will include descriptions of the organizational structure. The Quality Assurance Guidebook provides guidance of the methods for implementing a QM program with forms that instruct line management through the documentation process and relevant QM References.
- The organizational structure, functional responsibilities, levels of authority, and organizational interfaces must be defined and communicated.
- Individual organizations are encouraged and supported in their efforts to tailor QM implementation to their own activities.

The Laboratory Quality Management Support Group will assist managers in defining and developing QM program requirements so that the level of formality is commensurate with the level of risk. The customer focus on quality values will be communicated to and reinforced throughout the entire work force.

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### DOE "buzz words"

**NOTE:** Throughout DOE documents, Federal regulations, and other documents, "buzz word" phrases have certain meaning. Phrases like; "commensurate with the importance," and "commensurate with the level of risk" usually indicate that a *Graded Approach* is required to determine the degree of formality. *Graded Approach* is discussed on page three of the introduction to this Guidebook.

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### QM Support Group assistance

The Quality Management Support Group will assist managers in applying QM program requirements so that the level of formality is commensurate with the level of risk, based on a graded approach as described in the Summary Steps for Developing a QM Program (p. 7) and the *Quality Management Plan*.

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## IMPLEMENTATION GUIDANCE

### Guidebook Model explained

### QA vs. QM

**NOTE:** The following section is taken directly from the implementation guide for the codified Federal Regulation 10 CFR 830.120, guide G-830.120-REV.0, as a model for providing guidance to the manager interspersed with "Tips," in italics, applicable to Los Alamos National Laboratory. Footnotes have been added to give information or clarify the DOE guidance. Since the Rule, 10 CFR 830.120, and the Order, DOE Order 5700.6C, are so similar, developing and implementing a quality program for either nuclear or non-nuclear facilities should be only a matter of emphasis. See QM Reference 4. Because this *Guidebook* is intended to fulfill the requirements for the Federal Regulation, "Quality Assurance" is used instead of "Quality Management." For the purposes of this *Guidebook* "Quality Assurance," or "QA", is considered synonymous with "Quality Management," or "QM."

**Guide  
modifications**

NOTE: As it applies to Los Alamos, and in the interest of clarity, it was necessary to change some of the precise wording of the DOE Implementation Guide. Careful attention to editing assured that the meaning remained the same.

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**1. PROGRAM**  
**1.1 Introduction**

**Deming quote on  
leadership**

<sup>5</sup>*"The job of management is not supervision, but leadership. Management must work on sources of improvement, the intent of quality of product and of service, and on the translation of the intent into design and actual product. The required transformation of Western style of management requires that managers be leaders. Focus on outcome (management by numbers, **MBO**, work standards, meet specifications, zero defects, appraisal of performance) must be abolished, leadership put in place."*

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**Quality - principal  
factor of  
performance**

The principal factor reflecting the performance of an organization is the quality of its products and services. Criterion 1 requires that an organization develop and maintain an effective management system with the goal of ensuring safe, reliable products and services that meet or exceed the customer's requirements, needs, and expectation. The management system should include the methods for managing, performing, and assessing the adequacy of work, including work assigned to parties outside the organization.

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The management system should focus on accomplishing the mission as outlined in the organization's strategic plan. The management system applies to every component and employee of the organization, and includes the organizational structure, functional responsibilities, levels of authority, and interfaces.

**Implementing  
Criterion One**

*Tip: (Fully supports both the Rule and Order Criterion 1 requirements). As you can see , the Implementation Guide directly supports the Rule and Order. The Director's Policy 110, "Quality," and the Laboratory's Quality Assurance Management Plan (QAMP) reflect the commitment by the Laboratory to Quality Management as mentioned in the introduction, "The Guidebook Approach." Developing and implementing a Quality Management program begins with describing how work in the program is or will be managed, performed and assessed. Any program in progress has to have, at least at some level, addressed most of the requirements of the Rule and Order. As an example managers of Research and Development programs should consider the following: (1) what design standards will be used, (2) are there any additional requirements on procurement than BUS-5 already has, (3) other than accepted science techniques, are there any specific processes that need to be carefully defined. Therefore, taking credit for what you are actually doing , and using the steps outlined in this Guidebook, helps you avoid implementing a new, and perhaps costly, program. The DOE Standard, DOE-ER-STD-6001-92, included in the QM References will help stimulate thinking on subjects that need to be addressed. Meeting the requirements of criterion 1 is basically a description of your organization, and how you intend to manage it. Describing the results of going through "Summary Steps for Developing a QM Program" (see page 6 of this Guidebook), you should be able to address the issues of, and satisfy criterion 1.*

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**1.2 Responsibilities**

**Management  
responsibilities**

Management retains the primary responsibility and is accountable for the scope and implementation of the management system. However, every individual in the organization is responsible for achieving quality in his or

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<sup>5</sup> Deming, "Institute Leadership," point 7 of his 14 points, p. 54.

her activities. Management should promote effective achievement of performance objectives through the:

- establishment of task assignments;
- identification of lines of communication; and
- determination and provision of the necessary resources and environment to accomplish the required activities.

Management should ensure that all personnel understand and implement the management system.

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#### **Involving all Personnel**

*Tip: (This supports the general requirements of both the Rule and Order). Management should use personnel training sessions to inform them of those aspects of the Quality Management Program that directly affect them., e.g. work procedures. The object is to implement an effective management system , understood by all, so the program mission may be completed efficiently with due consideration for the safety of workers, the public, and environment.*

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### **1.3 Graded Approach**

#### **Graded Approach to determine level of effort needed**

The scope and depth of the management system's application of requirements to a specific activity should be determined by the use of a grading process. The grading process provides the flexibility to design controls that best suit the facility or activity. The graded approach process should determine the appropriate level of effort necessary to attain and document the requirements established through the consideration of prescribed factors. This process is based on a prescribed facility-specific or activity-specific factors such as the:

- level of risk;
- age, status, and condition of a facility or process;
- history of problems at a site or facility;
- adequacy of existing safety documentation; and
- complexity of products or services involved.

*Tip: A discussion of Graded Approach is included in page three of this Guidebook.*

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### **1.4 Applicable Standards**

#### **Deming's comment on government regulations and standards**

*6 "... government regulations and standards must have operational meaning, in order to be enforced. Conformance can be judged only in terms of a test and a criterion. The criteria and tests must be in statistical terms to have a meaning. A regulation or standard that is not so expressed will be devoid of meaning. A regulation without meaning can have no legal force."*

The following consensus standards provide acceptable methods for implementing many of the requirements of 10 CFR Part 830.120. No single standard fully meets all of the requirements. The principles, recommended approaches, and applications contained in these standards may be used in conjunction with 10 CFR Part 830.120 to develop an effective management system to achieve quality.

1. International Standard ISO 9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality System Elements-Guidelines, Section 4, "Management Responsibility," and Section 5, "Quality System Principles."
2. DOE-ER-STD-6001-92, dated June 1992, Implementation Guide for Quality Assurance Programs for Basic and Applied Research.

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<sup>6</sup> Deming, p. 297.

3. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Basic Requirements 1, "Organization," and 2, "Quality Assurance Program;" the supplementary requirements contained in Supplement 1S-1; and the non mandatory guidance contained in Appendix 1A-1.

***NOTE:** The latest issue of NQA-1 was in 1994. It includes revisions of the former NQA-1 (Quality Assurance Requirements for Nuclear Facility Applications) as Part I, NQA-2 (Quality Assurance Requirements for Nuclear Facility Applications), as Part II. NQA-3 has been dropped from NQA-1. Salient features are to be included in a later version.*

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## 1.5 References

1. International Atomic Energy Agency (IAEA) Safety Guide 50-SG-QA1, to be issued, Establishing and Implementing a Quality Assurance Programme.
2. ANSI/ASQC E44-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.1, "Quality Management and Organization," Part A-2, "Quality System and Description," and Part A. Section 2.7, "Quality Planning."
3. DOE RW-0333P, dated December 18, 1992, Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program.
4. USNRC NUREG-0800, Revision 0, dated August 1990, Standard Review Plan, Section 17.3, "Quality Assurance Program Description."
5. ASME NQA-2-1989, Quality Assurance Requirements for Nuclear Facility Applications. (See note above on NQA-1-1994.)
6. ASME NQA-3-1989, Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories. (See note above on NQA-1-1994.)
7. Institute of Electrical and Electronics Engineers Standard, IEEE 730-1984, IEEE Standard for Software Quality Assurance Plans.
8. American Nuclear Society Standard ANS-3.2, Quality Assurance Requirements for Operating Nuclear Power Plants.

### PARTIAL LIST OF ADDITIONAL ORDERS, CODES, AND STANDARDS THAT MAY BE HELPFUL

*10 CFR 830.1 through 830.7, 830.100, and 830.120 published in the Federal Register Vol. 59, No. 65, April 5, 1994, pp. 15851 - 15853.*  
*DOE Order 4700.1, Project Management System*  
*DOE Order 5480.19, Conduct of Operations*  
*DOE Order 5480.23, Safety Analysis Reports*  
*MIL-Q9858A, Quality Program Requirements*  
*EPA QAMS 004, Guidelines and Specifications for Preparing QA Program Plans*  
*EPA QAMS 005, Interim Guidelines and Specifications for Preparing QA Project Plans*  
*EPA QAMS 530, Technical Guidance Document: Construction QA for Land Disposal Facilities*  
*EPA QAMS 540, Data Quality Objectives for Remedial Response Activities*  
*Applicable OSHA regulations.*

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### LABORATORY ORGANIZATIONAL CONTACT

Quality Management Support Group (ESH-14), (505) 665-5437

CRITERION 2

PERSONNEL TRAINING AND QUALIFICATION

Requirements for personnel training	Requirements from 10 CFR Part 830.120, (C), (1), (ii), and DOE Order 5700.6C, criterion 2: {1} <i>Personnel Training and Qualification.</i> Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. {2} Personnel shall be provided continuing training to ensure that job proficiency is maintained.
Criterion Two LANL Response	Response from the LANL Quality Assurance Management Plan (QAMP), page 3, section 4.2: <ul style="list-style-type: none"><li>• Laboratory employees will be qualified as necessary to perform assigned work.</li><li>• Sufficient management attention and resources will be applied to training and qualification to ensure that employees are adequately prepared to achieve the quality required in their assigned work.</li><li>• Procedures to assure that employees are qualified will be developed.</li><li>• Records will be created and maintained to preserve the basis for management judgment.</li><li>• Qualification requirements associated with special processes and certain inspection test, and assessment activities will be developed and implemented.</li><li>• Personnel performing work requiring special skills or abilities will be qualified before they perform the work.</li><li>• Personnel will be provided ongoing training as appropriate to ensure the standards in job proficiency are met.</li><li>• This training could include quality assurance training and quality improvement training as a method for enhancing performance.</li></ul>
DOE Order 5480.20	The Training and Development Office is responsible for all Laboratory training and operates in accordance with procedures meeting the requirements of DOE Order 5480.20. All training programs including those performed by other organizations are approved by this office.

IMPLEMENTATION GUIDANCE

See "NOTE:" at the bottom of page 12 in tabbed section 1.	
FROM THE 10 CFR 830.120 "IMPLEMENTATION GUIDE," G-830.129-REV.0	
2. PERSONNEL TRAINING AND QUALIFICATION.	
2.1 Introduction	
Fundamental training requirement	A fundamental requirement for effective accomplishment of any mission is that all personnel be capable of performing their assigned tasks. Qualification and training programs ensure that the required capabilities are achieved and maintained by personnel.
Deming's comment on training	Tip: (The intent of this statement fully supports the requirements of the Rule.) <sup>7</sup> "Training must be totally reconstructed. Management needs training to learn about the company, all the way from incoming material to customer. A central problem is need for appreciation of variation."
2.2 Responsibilities	
Management's responsibility	Management should commit resources to facilitate the training and qualification processes, provide qualification and training requirements for personnel in their organizations, and ensure that personnel hired or transferred into positions meet the appropriate requirements. Each level of the organization should adequately describe specific

<sup>7</sup> Deming, "Institute Training On the job," point 6 of his 14 points, p. 54.

training and qualification processes. These descriptions should include requirements, interfaces, training methods, and training responsibilities and duties of line and training organizations.

#### Management's authority

*Tip: Managers should have the authority to decide on the qualifications of the personnel in their organizations. Technical managers at Los Alamos almost always have a complete understanding of the requirements of all organizational positions and, are able to decide organizational staffing. This is particularly true where the staff is multi-disciplinary and one person may be expert in more than one field.*

#### Training exclusion for SMEs

*Experts, who have contributed and are continuing to contribute original work in their technical fields, shouldn't have to take the required training in their respective fields. In P Division, managers argued that staff who contributed to writing the RADCON Manual shouldn't be required to take the training. DOE accepted this argument.*

### 2.3 Qualification of Personnel

#### Procedure development

Policies and procedures that describe personnel selection requirements should be established for each position. These should include the minimum applicable requirements for education, experience, and physical condition. Management should determine that personnel are suitably qualified to accomplish their assigned tasks. Personnel may be qualified by:

- considering previous experience, education, and training;
- demonstrating and testing to verify previously acquired skills; or
- completing a training or qualification program.

This determination should be accomplished before personnel are allowed to perform the work for which they are being qualified.

#### A successful LANL staffing method

*Tip: One method of staffing an organization that has been successful at Los Alamos, particularly with a versatile staff, is to use a matrix showing disciplines required versus personnel expertise. Such a matrix was developed at Los Alamos in the New Production Reactor Safety Project Office, between 1989 to 1991. Fifty-four disciplines were filled by a diverse versatile staff of about 35 people, NPR/SPO Procedure "Safety Reviewer Certification," No. LA-NPR-QA-3.3.*

#### Legal /ethical considerations of testing personnel

*<sup>8</sup> It is important that management give full attention to the legal and ethical aspects of testing. While the legal and ethical considerations concerning tests are consistent with the scientific approach, they are given special emphasis because of the major problems and criticisms that have arisen in connection with the use of tests." . . . Any test which adversely affects the employment status of groups protected by Title VII of the Civil Rights Act must be validated as an affective and significant predictor of effective job performance."*

### 2.4 Training

#### Training should: 1. provide knowledge

Training should provide knowledge of the correct processes and methods to accomplish assigned tasks. It should also provide an understanding of the fundamentals of the work, the context within which the work is performed, and the reasons for any special work requirements.

#### 2. address issues

Training goals, lesson plans, and other training materials should be consistently developed, reviewed by subject

<sup>8</sup> *Personnel Management*, by Dr. Herbert J. Chruden and Dr. Arthur W. Sherman, Jr., South-Western Publishing Co., Cincinnati, OH, 1976, p. 159 and p. 160.

matter experts, approved by management, and used to effectively deliver training. Training materials should be controlled to ensure that the latest approved versions are used.

### 3. be monitored

Training effectiveness should be constantly monitored. Worker performance should be evaluated to ensure that the training program conveys all required knowledge and skills. Feedback from personnel performance, former trainees, and supervisors should be used to determine effectiveness of training. The results of these evaluations should be used as the basis for improving the training program. Training usually falls within three categories: project specific, site specific, and institutional.

### 4. consider training required

Project-specific training should impart the knowledge required for the employee to practice his/her knowledge or skills toward the successful completion of the mission. This training might include mission, goals methods, requirements, process metrics, and skills. Project-specific training requirements should be defined by project management and workers.

Site-specific training should convey the safety, security, and operations knowledge required to enter a specific site. The site owner is responsible for defining training requirements and ensuring that the training is administered.

Institutional training should convey general information about the organization's mission, vision, goals, and management system. It may also include general knowledge or skills training.

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### Training and Development Office

*Tip: Working with the Laboratory's Training and Development Office will help in assuring that proper institutional training is achieved. Site-specific and project-specific training by their very nature must be directed from within the organization. Deming's quality principles are condensed to 14 points that are necessary for the transformation to a quality oriented organization. Point 6 says, 9<sup>9</sup>"Institute training on the job."*

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### Assessing Training

**10**<sup>10</sup>"Assessing Training needs consists of a systematic, threefold approach: (1) determining where within the organization training emphasis can and should be placed, (2) determining what the content of training programs should be, based upon a study of the tasks or duties involved, and (3) determining what skills, knowledge, or attitudes an individual employee must develop if he or she is to perform the assigned tasks or job duties effectively."

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## 2.5 Training Plans

### Training plans for all personnel

Training plans should be prepared for all personnel. The content of initial training plans should prepare personnel to perform the job. The content of continuing training plans should maintain and promote progressive improvement in incumbent job performance. Training plans may also provide employee satisfaction and interest for further self enhancement., In this way, training plans can be valuable in motivating personnel to develop enhanced technical, managerial, or other skills capabilities, and in tracking and documenting such development.

In the generation of a training plan, the manager and worker should consider all types of available training. Current facility, site, or organization procedures; technical and professional references; and past organization/industry experience should also be used to identify training plan content.

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### Need for continued upgraded training,

*Tip: Particularly at Los Alamos, as rapidly as technology changes, both jobs and tools change, and continuous education is necessary. However, there are some jobs at Los Alamos that are production. It is obvious that until a worker has become proficient with his or her particular job, training will be beneficial. Deming has an interesting*

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<sup>9</sup> Deming, "Institute Training On the job," point 6 of his 14 points, p. 23.

<sup>10</sup> Chruden and Sherman, p. 177.

observation to training. He says <sup>II</sup>"Anyone, when he has brought his work to a state of statistical control, whether he was trained well or badly, is in a rut." He goes on further to say, "Once the learning curve levels off, a control chart will indicate whether and when a person has reached the state of statistical control." He finally says that to, "charge him with faults of the system" [is an example of bad management]".

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## 2.6 Instructors

### **Instructors should be Subject Matter Experts (SMEs)**

Instructors may be training providers or qualified members of the organization requiring training. Instructors should possess technical knowledge, experience, and development and instructional skills. Instructor training should be based, in part, on the results of instructor evaluations and training on new methods and equipment.

*Tip: Again, for site-specific and project-specific training, technical managers at Los Alamos should be able to determine the qualifications of instructors for their organizations. However, do not rule out the fact that there may be Subject Matter Experts (SMEs) in other parts of the Laboratory. Instructors from external organizations may add fresh insights to subjects.*

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## 2.7 Applicable Standards

The following consensus standards provide acceptable methods for implementing many of the requirements of criterion 2. No single standard fully meets all of the requirements. The principles, recommended approaches, and applications contained in these standards may be used in conjunction with 10 CFR Part 830.120 in the development of an effective personnel qualification and training program.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.18, "Training."
2. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality system Elements-Guidelines, Section 18.1, "Training" and Section 18.2, "Qualification."
3. DOE-STD-1008-92, DOE Guideline, dated July 1992, Guide to Good Practices for On-Training of Technical Staff and Managers.
4. DOE-STD-1012-92, DOE Guideline Dated July 1992, Guide to Good Practices for On-The-Job Training.
5. DOE-STD-1005-92, DOE Guideline Dated July 1992, Guide to Good Practices for Developing Learning Objectives.
6. DOE-STD-1006-92, DOE Guideline Dated July 1992, Guide to Good Practices: Evaluation Instrument Examples.
7. DOE-STD-1007-92, DOE Guideline Dated July 1992, Guide to Good Practices for Teamwork Training and Diagnostic Skills Development.
8. DOE-STD-1011-92, DOE Guideline Dated July 1992, Guide to Good Practices for the Design, Development, and Implementation of Examinations.
9. NE-STD-1002-91, dated November 1991, Guide to Good Practices for Training and Qualification of Chemical Operators.

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<sup>II</sup> Deming, pp. 249 - 250.

10. NE-STD-1003-91, dated November 1991, Guide to Good Practices for Training and Qualification of Maintenance Personnel.
  11. ANSI/ANS-3.1-1987, American National Standard for Selection, Qualification and Training of Personnel for Nuclear Power Plants.
  12. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Supplements 2S-1, 2S-2, 2S-3, AND 2S-4, and appendices 2A-1, AND 2A-2.  
(See note on NQA-1-1994, page 15.)
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## 2.8 References

1. DOE/NE-0101T, TAP-1 - Training Program Manual, U.S. Department of Energy, Assistant Secretary for Nuclear Energy, July 1991.
2. DOE/NE-0102T, TAP-2 - Performance-based Training Manual, U.S. Department of Energy, Assistant Secretary for Nuclear Energy, July 1991.
3. DOE/NE-0103T, TAP-3 - Training Program Support Manual, U.S. Department of Energy, Assistant Secretary for Nuclear Energy, July 1991.
4. DOE-ER-STD-6001-92, dated June 1992, Implementation Guide for Quality Assurance Programs for Basic and Applied Research, Page 6 - 7.
5. IAEA Safety Guide 50-SG-QA-2, to be issued, Establishing and Implementing a Quality Assurance Programme, Training Section, and Annex 2 requirement on training.

For some specific skilled work tasks, useful practical principles and applications are contained in standards and guides prepared by industry and professional organizations such as the American Society of Mechanical Engineers (ASME), the American Welding Society (AWS), the Institute for Nuclear Power Operations (INPO), the American Society for Testing Materials (ASTM), and the Electric Power Research Institute (EPRI). Particularly useful examples include the qualification requirements in the American Society of Nondestructive Testing (ASNT) Standard ASNT-TC-1A, and in the ASME Boiler and Pressure Vessel Code, Sections V and IX.

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### PARTIAL LIST OF ADDITIONAL ORDERS, CODES, AND STANDARDS THAT MAY BE HELPFUL

*DOE Order 5480.20, Personnel Selection, Qualification, and Training, and Staffing Requirements at DOE Reactor and Non-Reactor Nuclear Facilities*

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### LABORATORY ORGANIZATIONAL CONTACT

Training and Development Office (TDO), (505) 665-6945

## CRITERION 3      QUALITY IMPROVEMENT

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### Requirement to detect and prevent quality problems

Requirements from 10 CFR Part 830.120, (C), (1), (iii), and DOE Order 5700.6C, criterion 3:

- {1} Quality Improvement. Processes to detect and prevent quality problems shall be established and implemented. (From DOE Order 5700.6C; The organization shall establish and implement processes to detect and prevent quality problems and to ensure quality improvement.)
  - {2} Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. (From the DOE Order; this requirement ends with "corrected.")
  - {3} Correction shall include identifying the causes of problems and working to prevent recurrence.
  - {4} Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items and processes needing improvement. (The DOE Order reads; "Item reliability" instead of "Item characteristics.")
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### Initiating Quality Improvement

### Criterion two LANL response

Response from the LANL Quality Assurance Management Plan (QAMP), page 3, section 4.3:

- To enhance operational performance and reduce process variability, methods will be established to identify, report, correct, and trend conditions adverse to quality. Currently, each operation or organization is responsible for its own non-conformance reporting procedure.
- As we proceed, (see Note at the end of this paragraph) a formalized procedure will develop that will institutionalize the reporting method.
- Senior management is responsible for providing overall direction of the improvement program and recognizes that prompt identification and documentation of deficiencies, coupled with the identification and correction of the root causes, are key aspects of quality improvement.
- Management at all levels will endorse and promote an environment in which all personnel are expected to identify nonconforming items or activities and potential areas for improvement.
- The Laboratory Quality Management Support Group will maintain copies of all nonconformance reports in order to establish causes for them, thereby helping to prevent recurrence.

(Note: A portion of this effort as related to the requirements of 10 CFR 830.122, "Defect Identification" and 10 CFR 830.350 "Reporting Operational Occurrences" will be assumed before the next revision of this procedure by the occurrence reporting group.)

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## IMPLEMENTATION GUIDANCE

See "NOTE:" at the bottom of page 12 in tabbed section 1.

FROM THE 10 CFR 830.120 "IMPLEMENTATION GUIDE," G-830.129-REV.0

## 3. QUALITY IMPROVEMENT

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### 3.1 Introduction

#### Premise of quality improvement

Quality improvement is based on the premise that all work activities can be planned, performed, measured, and improved. Management is responsible for building a culture in which improvement is continuous and an integral part of the organization. In promoting that culture, management should encourage the development and exploration of new ideas. The continuous improvement effort should increase worker awareness of the importance of quality and emphasize enhanced product and process safety and reliability. It should also promote a work environment in which all personnel will readily identify nonconforming items and potential areas for improvement.

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<b>Management improvement policy</b>	Management policy for continuous improvement should encourage the development and exploration of new ideas for improvement. Management policy for continuous improvement should be documented and communicated to all levels of the organization. The policy should make clear that the responsibility for improvement rests with each individual and organizational element and cannot be delegated to a particular person or group within the organization.
<b>DOE improvement focus</b>	The continuous improvement approach focuses on problem prevention, corrective action, and performance improvement rather than relying on post-process inspection to prevent defective items from reaching customers. Process performance should be continuously measured and evaluated to identify improvement opportunities. Each manager is responsible for managing process quality within his or her organization. Each worker should know how his or her process contributes to the strategic goals of the organization.
<b>Going beyond status quo</b>	<p><i>Tip: All too often quality improvement evolves into being nothing more than corrective action dealing with nonconformances, deficiencies, and concerns. This type of quality improvement is simply minimizing process variation within a stable system. It is what Juran refers to as solving the sporadic problem and Deming refers to as a special cause, the remedy is to return the process or system into the status quo. The techniques of identifying conditions adverse to quality, statistical process control, tracking, trending, root cause analysis, etc. are indeed necessary for quality improvement and usually are aimed at correcting the sporadic problem.</i></p>
<b>Bringing creativity into quality improvement</b>	<p><i>Innovative thinking takes quality improvement out of the mundane and brings it into the realm of creativity. <sup>12</sup>This is what Juran refers to as solving the chronic problem, Deming calls it the common problem, namely changing the status quo. Involving the customer in the process of improving products may help in changing the status quo. After all, it is the customer, and only the customer, who really defines quality. Without feedback from the customer, what appears to be quality improvement may not be quality improvement at all, but only a variation of corrective action.</i></p>
<b>Juran and Deming recognize need for quality improvement</b>	<p><i>Both Juran and Deming devote considerable portions of their books specifically to quality improvement.: in Juran chapters 5 and 6, and in Deming chapters 11,12, and 16. Quality Improvement is not necessarily a simple process. In fact in Deming's book he says,</i></p> <p><i><sup>13</sup>"It would be incorrect to suppose that improvement of a system is always so stupidly simple as the illustrations shown in this chapter and in other parts of this book. Improvement may require simultaneous tests of two or more factors, by appropriate statistical design."</i></p>
<b>3.2 Continuous Improvement</b>	
<b>Process performance</b>	Process performance should be continuously evaluated to identify actions that can be taken to improve output quality. These evaluations may be based on quantitative and/or qualitative information obtained from monitoring process performance indicators and from management and independent assessments. The areas of performance that most directly affect the process's ability to meet customer requirements and expectations
<b>satisfying customer</b>	should receive the greatest emphasis in process improvement. Any failures to meet customer requirements or expectations should be identified, corrected, and prevented from recurrence.
<b>Plan-Do-Check-Act cycle</b>	One approach to process improvement is the Plan-Do-Check-Act (PDCA) cycle. It is a formalized technique for referring to the continuous process of studying a work process and finding new ways to improve performance.

<sup>12</sup> Juran, p. - 99, Deming, pp. 310 - 312.

<sup>13</sup> Deming, p. 371.

The PDCA cycle is an ongoing pursuit of the planning, implementing, and evaluating of process improvements. Workers should be empowered through training to operate processes, identify process deficiencies, develop improvement approaches, implement solutions, and evaluate process improvements. Open communications across all levels of the organization are essential for continuous improvements.

The "Plan" phase should define what the process is required to accomplish. The process should be designed to be results-oriented and based on desired identification, desired output, process steps, process capability, performance indicators, resources, and process baseline.

During the "Do" or performance phase, work is accomplished to produce goods or services for the customer. Process improvements are implemented.

The "Check" phase should measure the process operation. Process performance indicators should be monitored and results examined for indications of required adjustments. The process should be operating to a performance baseline and the workers should be alert for problems or improvement opportunities.

The "Act" phase should determine how the process is working and if further process refinements are required. The qualitative and quantitative data gathered is analyzed and results compared to the desired process results and to results from similar processes. Trends in productivity and quality can be identified. If the need for further process modifications are indicated, concepts should be generated to feed to the planning phase for further consideration.

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#### Deming's explanation of the Shewhart cycle

*Tip: Though commonly referred to as the Deming Cycle, Deming himself never referred to it as such, the PDCA cycle is actually known as the Shewhart Cycle. It was first introduced by Walter A. Shewhart in a paper, "Statistical Method from the Viewpoint of Quality Control," published by the Graduate School, Department of Agriculture, Washington, D. C., 1939, and again by Dover in 1986. The Japanese eventually called it the Deming Cycle, though Deming himself continued to refer to it as the Shewhart Cycle.*

*"In the Shewhart Cycle the following steps are described by Deming;*

*(1) What could be the most important accomplishments of this team? What changes might be desirable? What data are available? Are new observations needed? If yes, plan a change or test. Decide how to use the observations.*

*(2) Carry out the change or test decided upon, **preferably on a small scale.***

*(3) Observe the effects of the change or test.*

*(4) Study the results. What did we learn? What can we predict?*

**14". . .The Shewhart Cycle will be helpful as a procedure to follow for improvement of any stage; also as a procedure for finding a special cause detected by statistical signal"**

*The description by Deming is slightly different in emphasis than the DOE guidance. One can see a strong parallel to the Scientific Method in Deming's description. As in scientific study, a hypothesis or theory is deduced from step three in step four. The cycle is then repeated to test the hypothesis.*

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### 3.3 Applicable Standards

There are no directly applicable standards on the subject of Quality Improvement: However, there are some reference materials that provide useful information on the approach, and there are standards that cover specific limited areas such as statistics, root cause analysis, or the control of nonconforming materials. Examples of those documents are listed below under references.

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<sup>14</sup> Deming, p. 88.

### 3.4 References

1. Malcolm Baldrige National Quality Award Criteria, U.S. Department of Commerce Technology Administration, National Institute of Standards and Technology, 1993.
2. Quality Improvement Tools, Juran Institute, Wilton, CT, 1989.
3. DOE Student Training Manual, Criterion 3, Quality Improvement Course, Handbook of Concepts, Tools, and Techniques.
4. DOE-STD-1048-92, Dated December 1, 1992, Performance Indicators Guidance Document.
5. DOE-NE-STD-1004-92, Dated February 1, 1992, Root Cause Analysis Guidance Document.
6. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality system Elements-Guidelines, Section 14, "Nonconformity," and Section 15, "Corrective Action."
7. IAEA Safety Guide 50-SG-QA12, to be issued, Nonconformance Control and Corrective Action.
8. ANSI/ASQC Standard E4-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.10, "Quality Improvement."
9. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Basic Requirements 15, "Control of Nonconforming Items," with Supplement 15S-1, and Basic Requirements 16, "Corrective Actions."  
(See note on NQA-1-1994, page 15.)
10. DOE/HR-0066, dated December 1993, Total Quality Management Implementation Guidelines.

#### LABORATORY ORGANIZATIONAL CONTACTS

Quality Management Support Group (ESH-14), (505) 665-5437  
Statistics Group (TSA-1), (505) 667-3308

## CRITERION 4 DOCUMENTS AND RECORDS

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### Requirements for documents and records

Requirements from 10 CFR Part 830.120, (C), (1), (iv), and DOE Order 5700.6C, criterion 4:

- {1} *Documents and Records*. Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.
  - {2} Records shall be specified, prepared, reviewed, approved, and maintained.
- 

### Criterion Four LANL response

Response from the LANL Quality Assurance Management Plan (QAMP), page 3, section 4.4:

- Systems and procedures will be established to ensure that documents generated subject to this program are prepared, reviewed, approved, revised, and distributed with appropriate controls to personnel performing the work. Documents requiring formal control will be identified. Documents include, but are not limited to, procedures, standards, instructions, manuals, drawings, computer codes, purchase orders, vendor manuals, design-basis documents, safety analyses and related reports, QM plans, and other documents important to the implementation of the work.
  - Systems and procedures will be established to ensure that appropriate records are generated, collected, reviewed, approved, properly stored, and legible. Records requiring formal control will be identified. Retention periods will be identified, and records will be indexed for accountability and retrievability. Appropriate guidance must exist to assure physical protection, preservation, and traceability. Computer hardware and software used to maintain, index, store, or access records will be controlled to ensure accountability, reproducibility, and protection from loss.
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## IMPLEMENTATION GUIDANCE

See "NOTE:" at the bottom of page 12 in tabbed section 1.

FROM THE 10 CFR 830.120 "IMPLEMENTATION GUIDE," G-830.120-REV.0

### 4. DOCUMENTS AND RECORDS

#### 4.1 Introduction

##### Necessity of Documents and records

Documents and records are required to manage, perform, and assess work. Management should identify any documents that must be controlled and records that must be generated, and should commit the resources necessary to accomplish the document and record requirements.

*Tip: (The intent of this statement fully supports the requirements of the Rule). In the past the following statement has been alluded to as unwritten DOE policy, and is probably true:*

***"If it hasn't been documented, it hasn't been done!"***

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#### 4.2 Documents

##### document control process

Documents may be required by organizations, projects, or programs to control policy, administrative, or technical information. A document may describe work to be done, data to be used at different locations or by different people, or, in changing situations, data that is controlled from time to time for reference purposes. A document control process should establish requirements to release documents for distribution, identify recipients, specify actions to be taken with existing documents when revisions are released for distribution or documents are canceled, and identify unique revisions and copies.

<b>Organizational document control</b>	<p>Document control requirements should be defined by each organizational unit. Although the actual process may be supplied internally or externally, the organizational unit is responsible for ensuring that its requirements are being met.</p> <p><u>Note:</u> The Tips in this section are not changed from the Quality Assurance Guidebook, Rev 0. The word "Tip" has been changed to "Comment" to avoid confusion.</p>
<b>Establishing a document control process</b>	<p>a. A process should be established and implemented to control preparation, review, approval, issuance, use, and revision of documents that establish policies. prescribe activities, specify requirements, or establish design.  <u>Comment:</u> The QM Program should include a document control system. Documents such as work instructions, manuals, and procedures should be prepared according to identified guidelines. They should undergo a formal review and approval process, be issued according to a defined process, and be used and revised as described in the QM Program Plan. An effective document control system should minimize the risk that employees will work from outdated instructions or procedures.</p>
<b>Document control system scope</b>	<p>b. The scope of the document control system should be defined. Examples of documents to be controlled include drawings, data files (including various media), calculations, specifications, computer codes, purchase orders and related documents, vendor-supplied documents, procedures, work instructions, operator aids, and data sheets.  <u>Comment:</u> The list of controlled documents may include other documents. If a document is significant to the organization or program, then it should be controlled commensurate with the level of its importance.</p>
<b>Document revision review and approval</b>	<p>c. Revisions to controlled documents should be reviewed and approved by the organization that originally reviewed and approved the documents or a designated organization that is qualified and knowledgeable. Timeliness guidelines should be implemented for distribution of new or revised controlled documents.</p>
<b>Document distribution</b>	<p>d. Controlled documents should be distributed to and used by personnel performing work.  <u>Comment:</u> The QM Program Plan should address the control of document distribution and indicate the means by which distributed uncontrolled copies, if any, will be updated. Formal controlled copies of a document should be distributed to those responsible for the work's completion. Uncontrolled copies may be distributed, as needed, to the personnel actually performing the work.</p>
<b>Superseded documents controlled</b>	<p>e. Control of superseded and canceled documents should include measures to ensure that only correct documents are in use. Record copies should be marked "superseded" or "canceled" and kept for a specified retention period.  <u>Comment:</u> Only the originating organization is required to maintain record copies of canceled or superseded controlled documents. (Other organizations may keep copies of canceled or superseded documents, but they should document their procedures in their QM Program Plan.) The QM Program should include provisions to ensure that documents in use, including uncontrolled copies, are current. Responsibility for updating documents may be shared with those who have controlled copies. The QM Program Plan may specify that individuals receiving controlled copies are responsible for distributing updates of uncontrolled copies they have distributed.</p>

### 4.3 Records

#### Record information, and storage

A record contains information that is retained for its expected future value. Records should be sufficient to support technical and regulatory decisions. Records and documents may be electronically stored, written or printed, microfilm photographs, radiographs, or laser disks.

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#### Record maintenance

Records are compiled into a records management system that ensures appropriate records are maintained. The records system should include provisions for retention, protection, preservation, changing, traceability, accountability, and retrievability of records. While in storage, records should be protected from damage, loss, and deterioration. Evidentiary records should have appropriate procedures controlling media type, chain of custody, and confidentiality.

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#### Electronic processing

For records that require electronic processing control, the hardware and software required to maintain and access the records should be maintained and controlled to ensure that the records remain usable. These records include information recorded on magnetic media and optical disks.

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#### Records disposition

The National Archives and Records Administration (NARA) has final authority for approving the disposition of Government records. NARA publishes the General Records Schedule (GRS), and approves DOE unique records schedules. All records management systems should have schedules for records retention and disposition in accordance with the requirements of NARA and DOE 1324.2 (latest issue), "Records Disposition." Records management systems should address the requirements of DOE 1324.5 (latest issue), "Records Management Program." Applicable standards may differ in records management terminology from the NARA requirements. Care should be taken to ensure that the requirements of NARA, applicable standards, and any additional statutory requirements are met. Records retention times may also be included in contractual requirements.

Note: The Tips in this section are not changed from the Quality Assurance Guidebook, Rev 0. The word "Tip" has been changed to "Comment" to avoid confusion.

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#### Record control process

Comment: Records are "dead." They document events that occurred, conclusions that were reached, or analyses that were performed. Records document the history of a program.

- a. A process should be established and implemented to ensure that sufficient records (for example, records of design, environmental conditions, applied research and development, procurement, construction, data acquisition, assessments, inspection, testing, maintenance, and modification) are specified, prepared, reviewed, approved, and maintained to accurately reflect completed work. The maintenance of records should include provisions for retention, protection, preservation, traceability, accountability, and retrievability.

Comment: The QM Program Plan should specify how records should be identified and maintained to support current and completed work. Records maintenance specialists may assist managers in developing a records maintenance system.

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#### Special processing

- b. For records that require special processing control, such as computer codes or information on high density media or optical disks, hardware and software required to maintain and access records should be controlled to ensure records are usable.
- Comment: The QM Program Plan should include the location of the records and of any hardware or software required for retrieving them.
- 

#### Facilities, and General Records Schedule

- c. Records holding facilities are reserved for storage of inactive records and may not meet the physical requirements or have appropriate staff to maintain active records. Active records requiring special handling, storage, and processing should not be sent

to records holding facilities. Users should refer to the General Records Schedule (GRS) or DOE 1324.2A for retention and disposition of records.  
*Comment:* The QM Program Plan should specify the point at which active records become inactive (archived). Furthermore, it should describe the procedures used for storing and retrieving both active and inactive records. Records maintenance professionals may assist with storage and retrieval of inactive records (archives) at storage facilities.

**National Archives and Records Administration (NARA) authority**

- d. The National Archives and Records Administration (NARA) exercises final authority for approving the disposition of Government records. Use of the GRS, which is published by the NARA, and the DOE unique schedules approved by the NARA are mandatory.  
*Comment:* Records management professionals responsible for the Laboratory's records management system may assist with setting up a program's or organization's records management system.

**Meeting NARA and other standards**

- e. Some standards which provide interpretive quality assurance guidance may differ in records management terminology from the NARA requirements. In those instances, care should be taken to ensure that the requirements of both the NARA and standards are followed.

**4.4 Applicable**

**Standards.**

The following consensus standards provide acceptable methods for implementing many of the requirements of Criterion 4. No single standard fully meets all of the requirements. The principles and recommended approaches and applications contained in these standards may be used in conjunction with 10 CFR Part 830.120 in the establishment and implementation of an effective document control and records management system.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.5, "Document Control," and Section 4.16, "Quality Records."
2. ISO-9002-1987 (ANSI/ASQC Q92-1987), Quality Systems - Model for Quality Assurance in Production and Installation, Section 4.5, "Document Control," Section 4.16, "Quality Records."
3. ISO-9003-1987 (ANSI/ASQC Q93-1987), Quality Systems - Model for Quality Assurance in Final Inspection and Test, Section 4.3, "Document Control," and Section 4.10, "Quality Records."
4. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality System Elements-Guidelines, Section 17, "Quality Documentation and Records."
5. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Basic Requirements 6, "Document Control," and 17, "Quality Assurance Records," Supplements 6S-1 and 17S-1, and Appendix 17A-1.  
 (See note on NQA-1-1994, page 15.)

**4.5 References**

1. USNRC Regulatory Guide 1.28, dated August 1985, Quality Assurance Program Requirements (Design and Construction), Table 1, "Retention Times for Lifetime and Nonpermanent Records."

2. Title 44 United States Code (U.S.C.) Chapter 21, National Archives and Records Administration (NARA), which establishes certain authorities in the Archivist of the United States for the acceptance and preservation of records of a Federal agency.
3. Title 44 U.S.C. Chapter 33, Disposal of Records, which establishes the procedural requirements for obtaining authority from the Archivist for the disposal of Departmental records.
4. DOE-ER-STD-6001-92, dated June 1992, Implementation Guide for Quality Assurance Programs for Basic and Applied Research, Page 8.
5. IAEA Safety Guide 50-SG-QA-2, to be issued, Document Control and Records.

#### LABORATORY ORGANIZATIONAL CONTACT

Communications and Records Management Division (CIC-DO), (505) 667-5330  
Form revision, CIC-10, MS-C322, (505) 665-7900

## CRITERION 5 WORK PROCESSES

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### Work process requirements

Requirements from 10 CFR Part 830.120, (C), (1), (v), and DOE Order 5700.6C, criterion 5:

- {1} *Work Processes*. Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. (DOE Order is worded slightly differently but has exactly the same intent.)
  - {2} Items shall be identified and controlled to ensure their proper use.
  - {3} Items shall be maintained to prevent their damage, loss, or deterioration.
  - {4} Equipment used for process monitoring or data collection shall be calibrated and maintained.
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### Criterion Five LANL response

Response from the LANL Quality Assurance Management Plan (QAMP), page 3, section 4.5:

- Laboratory management, working with program sponsors, will ensure that work activities and processes are planned in advance and that each organization understands its role and the applicable standards and quality requirements.
  - The organization will identify work processes critical to mission accomplishment and document authorities, responsibilities, interfaces, procedures, standards and performance measures for these processes.
  - The calibration of monitoring and data collection equipment (M&DCE) and measuring and test equipment (M&TE) will be controlled as described in the Laboratory's *Calibration Handbook*.
  - The handbook requires that M&TE used as a basis for acceptance or testing be identified by line and technical management and that data objectives, required accuracy, and specific measuring equipment calibration requirements be identified.
  - Required procedures and training will be incorporated into the work plans, and individuals performing the work will be familiar with the tools, work processes, and specific quality requirements.
  - Critical work processes should be tracked and measured. Required inspections or test points will be identified and incorporated within the overall work plan.
  - Written procedures and standards will be developed to ensure that an auditable trail is maintained for critical items procured or fabricated.
  - Handling, storage, shipping, and packaging requirements will be identified and addressed. Procedures and standards will address unique requirements associated with items that require in-storage maintenance, that have a limited shelf life, or that pose a particular hazard to the environment, facilities, or personnel.
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## IMPLEMENTATION GUIDANCE

See "NOTE:" at the bottom of page 12 in tabbed section 1.

FROM THE 10 CFR 830.120 "IMPLEMENTATION GUIDE," G-830.120-REV.0

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## 5. WORK PROCESSES

### 5.1 Introduction

#### Work process defined

A work process includes all activities involved in performing defined tasks to achieve an objective. Work processes may include such activities as planning, scheduling, accounting, project management, design, analysis, fabrication, procurement, construction, installation, testing, operation, modification, maintenance, and decommissioning. The work process is a planned mix of people, equipment, environmental conditions, supply, management support, resources, and requirements. Each of these elements contributes to achieving process goals.

#### Work process metrics

*Tip: Work processes may be processes that produce either goods or services. Metrics can be established for all work processes, therefore, statistical process control can be applied to all work processes. Management must be careful about the way goals are*

established. As Deming says, <sup>15</sup>"Goals are necessary for you and me, but numerical goals set for other people, without a road map to reach the goal, have effects opposite to the effects sought."

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## 5.2 Management Responsibility

### Management involvement

Managers should routinely be involved in work processes to ensure that criteria for acceptable work performance are clearly defined. The manager is responsible for setting requirements and policies which control the conditions under which the work process is required to function. These conditions should be considered as an element affecting product and service output and quality.

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### Deming on leaders supervising

*Tip:* Not only should managers be involved in work processes, it is fallacious to entertain the thought that managers be excluded from involvement in work processes.  
<sup>16</sup>"Leaders must know the work they supervise."  
<sup>17</sup>"The complexity and volume of modern products usually requires a manufacturing process which is multi-departmental in scope. Design of the physical facilities for this process involves:

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### Juran and Gryna on process design

1. A Systems Design, which contemplates the entire progression of the product from purchased materials and components through finished goods.  
2. A set of designs for the various departmental processes, i.e., Unit Processes, which collectively carry out the broad concept of manufacture. Each unit process, in turn, can consist of multiple work stations, each of which carries out one or more production operations."  
At Los Alamos manufacturing volume is rarely great. However, in his book <sup>18</sup>Juran elaborates about process design. Process design, as requirements dictate, may require formal documentation. Procedures, especially for nuclear facilities, should be written to carefully describe the actual processes. Once processes become stable, statistical methods may be applied to assure minimization of process variation.

---

### Management responsibility for processes

The manager is responsible for planning and designing the work process. The required goals should be known in order to plan for the work processes. Work should be performed to prescribed standards, procedures, or instructions of a detail commensurate with the complexity and importance of the work. When possible, administrative controls should be simplified to minimize the impact of controls on the worker. Personnel performing a process should be included in process improvement activities. The work process should be designed to produce the desired quantity and quality of output.

### Use of Graded Approach

*Tip:* Designing should be done using a Graded Approach.

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### Placing/training qualified personnel

The manager is responsible for placing qualified personnel in positions to accomplish work and training them in the requirements of the job. Workers should be trained to new conditions if the work process is changed.

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<sup>15</sup> Deming, p. 69.

<sup>16</sup> Deming, p. 54.

<sup>17</sup> Juran and Gryna, p. 267.

<sup>18</sup> Juran and Gryna, pp. 264 - 313

### 5.3 Worker Responsibility

Workers are responsible for the quality of their own work. Workers should set goals for doing the work correctly the first time and contribute to improved work processes.

#### Challenge to managers

*Tip:* In a research and development context, "doing it right the first time" refers to using a systematic approach from the first stages of the project through its completion. <sup>19</sup>It is directed at management, not workers, and is intended to charge managers with the challenge of assuring that data be correct the first full operation of an apparatus. One must remember that in science, even negative results may constitute good science.

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#### Deming on slogans

About slogans such as "Do it right the first time," Deming says, <sup>20</sup>"Eliminate targets, slogans, exhortations, posters for the work force that urge them to increase productivity."

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#### Aguayo on slogans

Aguayo says, <sup>21</sup>"Slogans such as 'Quality is up to you' or 'Do it right the first time' sound benign, but **they're just not true**. Quality is made in the board room. A worker can deliver lower quality, but she cannot deliver better quality than the system allows!"

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#### Deming on posters

<sup>22</sup>"Posters that explain to everyone on the job what the management is doing month by month to (for example) purchase better quality of incoming materials from fewer suppliers, better maintenance, or to provide better training, or statistical aids and better supervision to improve quality and productivity, not by working harder but by working smarter, would be a totally different story: they would boost morale. People would then understand that the management is taking some responsibility for hang-ups and defects and is trying to remove obstacles. I have not yet seen any such posters."

---

#### Workers as prime resources

Workers should be considered as prime resources concerning the various aspects of their process. They understand how the process works and how metrics can best be applied. They are first-line contact with both customers and suppliers and possess first hand knowledge of the products and services being supplied to and by their process.

#### Removing barriers to pride of

*Tip:* Workers who are given a chance to take ownership of their work processes show pride in their work and, if empowered, improve work processes on their own. Deming, says, <sup>23</sup>"Remove barriers that rob the hourly worker of his right to pride of workmanship. The responsibility of supervisors must be changed from sheer numbers to quality."

*In addition, workers that not only understand their individual work processes, but also understand how their processes fit into the mission of the organization as a whole quite often can do a better job.*

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<sup>19</sup> *Quality Assurance Guidebook, Rev. 0*, Los Alamos National Laboratory, 1993, p. 14.

<sup>20</sup> Deming, p. 65.

<sup>21</sup> *Dr. Deming, the American Who Taught the Japanese About Quality*, by Rafael Aguayo, Carol Publishing Group, New York, NY., 1990, p. 202.

<sup>22</sup> Deming, pp. 68 - 69.

<sup>23</sup> Deming, point 12b of his 14 points, p. 64.

## 5.4 Work Process Documents

### Work process documentation

The manager should clearly identify authorities, responsibilities, and interfaces, both internal and external, regarding the work process in appropriate work process documents. Policies, procedures, goals, plans and any other information affecting a process should be clearly communicated to the personnel working within that process.

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### Workers' statistical control

*Tip:*     <sup>24</sup>"Workers who perform processes fall into two categories: they either have statistical control of their work or they do not. A basic principle presumed here is that no one should be blamed or penalized for performance that he can not govern."

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### Work process documents availability

Applicable work process documents should be readily accessible to the worker. Work process documents should be based on the skills of the workers using them and on the complexity and importance of the work. Work process documents should include any requirements for special processes that are highly dependent on the control of the process or the skill of the operator, and for which the quality of the product cannot be readily determined by inspection or test.

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### Work process documentation, design, training

*Tip:*     Processes that require formal documentation should be the result of a formal design cycle that includes all of those activities one normally attributes to the design function, see section 6.2, "Design Input." Design of work processes involves a determination of the required skills to perform the tasks necessary to complete the process. Work process documents should be based first on the complexity of the processes, then the skills of the workers using them commensurate with the importance or risk of the work. Workers should be trained and qualified to the processes. Workers using processes that have not been documented should be involved in developing the operating procedures so that the procedures accurately reflect the process as it proceeds from beginning to end. Workers may be helpful in developing process metrics, which will lead to minimizing process variation during future operations.

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### Prevention of incorrect work

Work process documents should address such process elements as methods to prevent the use of incorrect or defective items and to ensure items requiring traceability are identified and controlled. Documents should describe methods controlling packaging, shipping, receiving, storage, handling, cleaning, and preservation of items to prevent damage, loss, or deterioration.

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### Worker empowerment

*Tip:*     Workers should clearly be involved and empowered to identify nonconformances, and be involved in corrective actions. Finding and correcting problems shouldn't be a witch hunt. Witch hunting does not solve problems. A determination should be made if the nonconformance is a systemic problem, in which case the system needs to be changed. If a worker has created a nonconformance because of poor training, it is management's responsibility to institute proper training, not usually the worker's.

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### Training to fit worker

<sup>25</sup>"People learn in different ways. Some have difficulty to learn by written instructions (dyslexia). Others have difficulty to learn by the spoken word (dysphasia). Some people learn best by pictures; others by imitation; some by a combination of methods." Deming's point here, obviously, is to fit the training to the worker!

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<sup>24</sup> Deming, pp. 250 - 251.

<sup>25</sup> Deming, p. 52.

## ES&H Writer's guides/standards for procedures

*The Laboratory management has recognized the need for a consistent, formal process for evaluating, communicating, and implementing the ES&H related requirements and directives that come to the Laboratory from numerous sources, such as the Department of Energy and the University of California. As such the ES&H Writers Guide was written to help organizations within the Laboratory produce ES&H documents. Several organizations have produced their own Writer's guides. The ES&H Writers Guide is a good reference for either producing a writer's guide or writing ES&H documents, QA procedures, work process procedures, or technical procedures.*

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## 5.5 Applicable standards

The following consensus standards provide acceptable methods for implementing many of the requirements of Criterion 5, although none of the standards fully meets all of the requirements. The principles and recommended approaches and practices contained in these standards may be used in conjunction with 10 CFR Part 830.120 in developing effective work process controls.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.9, "Process Control."
  2. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality System Elements - Guidelines, Section 10.0, "Quality in Production," and Section 11.0, "Control of Production."
  3. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Basic Requirements 8, "Identification and Control of Items;" 9, "Control of Processes;" 13, "Handling, Storage, and Shipping;" and 15, "Control of Nonconforming Items;" and Supplements 9S-1, 12S-1, and 13S-1.  
(See note on NQA-1-1994, page 15.)
  4. DOE/RW/0333P, dated December 18, 1992 Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program, Section 9, "Control of Special Processes."
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## 5.6 References

- 1 DOE Student Training Manual, dated April 7, 1993, Management in the Work Process.
2. NUREG 1293, Revision 0, dated January 1989, Quality Assurance Guidance for Low Level Waste Disposal Facility, Section 9, "Control of Processes."
3. ANSI/ASQC Standard E4-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.8, "Quality Implementation of Work Processes."

### PARTIAL LIST OF ADDITIONAL ORDERS, CODES, AND STANDARDS THAT MAY BE HELPFUL

DOE Order 5480.22, Technical Safety Requirements  
DOE Order 5480.3A, Hazardous Materials Packaging and Transportation Safety  
DOE Order 4330.4A, Maintenance Management Program  
DOE Order 5480.4, Environmental Protection, Safety, and Health Protection Standards  
DOE Order 5480.5, Safety of Nuclear Facilities  
DOE Order 5480.19, Conduct of operations  
MIL-STD-45662A, Calibration Systems Requirements  
LALP-93-047, Calibration Handbook

#### LABORATORY ORGANIZATIONAL CONTACTS

Statistics Group (TSA-1), (505) 667-3308

Calibration Group (ESH-9), (505) 667-4864

Quality Management Support Group (ESH-14), (505) 665-5437

Instrumentation and Calibration Section, Health Physics Measurements Group (ESH-4), (505) 665-4010

## CRITERION 6      DESIGN

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### QM design requirements

Requirements from 10 CFR Part 830.120, (C), (1), (vi), and DOE Order 5700.6C, criterion 6:

- {1} *Design.* Items and processes shall be designed using sound engineering/scientific principles and appropriate standards.
  - {2} Design work, including changes, shall incorporate applicable requirements and design bases.
  - {3} Design interfaces shall be identified and controlled.
  - {4} The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work.
  - {5} Verification and validation work shall be completed before approval and implementation of the design.
- 

### Criterion six LANL response

Response from the LANL Quality Assurance Management Plan (QAMP), page 4, section 4.6:

- Design activities will be governed by graded procedures, as appropriate, to ensure that design standards and technical, safety, regulatory, operational, and maintenance requirements are appropriately incorporated and achieved using sound engineering and scientific principles.
  - Design control requirements for procured design services will be incorporated into procurement and contract specifications.
  - Design interfaces between interacting disciplines and design organizations will be defined relative to responsibilities, design reviews, design-basis exchange between responsible agencies, deliverables, and associated approvals.
  - The overall system will be designed to ensure that documents and records are appropriately generated, controlled, and retained; and to ensure the acceptability of the deliverable.
  - Design verification and validation will be completed by persons other than those who performed the work. This will be done before the approval and implementation of the design.
  - Design procedures will address design input, development, analysis, validation, and output to ensure that final designs and the resulting systems or facilities meet specified technical requirements, standards, and codes.
  - Design changes, including those made during fabrication or construction, subsequent modifications, and nonconforming items will be subject to design standards and controls consistent with those applied to the original design.
  - The adherence to the program will preclude the use of unverified design data and assure that appropriate verification or qualification testing is completed before design data are used in subsequent activities.
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## IMPLEMENTATION GUIDANCE

See "NOTE:" at the bottom of page 12 in tabbed section 1.

FROM THE 10 CFR 830.120 "IMPLEMENTATION GUIDE," G-830.120-REV.0

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## 6. DESIGN

### 6.1 Introduction

#### DOE requirements restated

Definition, control, and verification of design is necessary to ensure that systems, structures, and components fulfill contractual requirements and customer expectation. Design work should be based on sound engineering and scientific principles. A formal design process should be established which provides control of design inputs, outputs, verification, configuration and design changes, documentation, records, and technical and administrative interfaces.

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**Use of matrix for design interfaces**

*Tip: Defined interfaces are important to assure that persons who need to be are aware of information or decisions that may impact their responsibilities. A design interface control matrix is a chart that shows tasks, or sub-systems on both axes and indicates which may conflict with one another. Such a chart defines interfaces of project, program parts, or sub-systems.*

**Uniqueness of Design function at Los Alamos**

*It is clear from the above discussion that the team that wrote the implementation guidance, as expected, had in mind facilities that produce items that are assembled, fabricated, constructed, manufactured, or produced either in mass or one of a kind. Because Los Alamos is technically oriented, we tend to think in the same terms. The design process principles, however, may be applied to services as well as goods. Administrative processes as well as technical processes may also be designed, approved, controlled, or changed as needs require.*

**DOE Order 6430.1A consideration**

Systems, structures, and components important to safety should be subject to more stringent operational criteria and verification requirements than those not important to safety. DOE 6430.1A ( or latest issue), "General Design Criteria," provides a definition of safety class and examples of systems, structures, and components that are normally designated as safety class in DOE facilities. Safety Analysis Reports should exist for each DOE nuclear facility which define that facility's systems, structures, and components important to safety.

**SAR Reporting as 10CFR830.110**

*Tip: A Safety Analysis Report may be required for both nuclear facilities and Non-Nuclear Facilities (NNF). The DOE Order, Safety Analysis Reporting, 5480.23, should be followed. As a codified rule, it is 10 CFR 830.110.*

**DOE Order 4330.4A**

Designs should provide for appropriate inspection, testing, and maintenance to ensure continuing reliability and safety of the system, structure, or component. The design should consider the expected use and life expectancy of the system, structure, or component in order to address appropriate disassembly and disposal requirements.

*Tip: For either nuclear facilities and Non-Nuclear Facilities (NNF), "Class A" and "Class B" equipment must be maintained. The Doe Order regarding maintenance of equipment is 4330.4A, Maintenance Management Program. It is now also a codified rule, 10 CFR 830.340.*

Design records may include design input, calculations and analyses, engineering reports, design output documentation, design verification documentation, design change documentation, and design revisions.

**DOE Order 4700.1 used with 6430.1A**

*Tip: (The intent of this statement fully supports the requirements of the Rule). Since many design processes are intimate with project management, use of DOE Order 4700.1, Project Management Systems, is a good supplement to DOE Order 6430.1., General Design Criteria. At Los Alamos, the design team may include a variety of disciplines and people; Theoretical Physicists, experimental physicists, engineers (electrical, mechanical, and civil to mention a few), facilities engineering, procurement, and vendors., not to mention the DOE itself. The supplier-customer model, expounded by AT&T, and expanded by the DOE, may become complicated and convoluted. Nevertheless, experience has shown that in a spirit of cooperation, many projects have been completed on time and within budget, e.g. the Meson Physics Facility. Making an effort to harbor a team spirit and avoid developing situations that include adversarial relationships can lead to win-win situations for Los Alamos, the DOE, and vendors alike.*

**Vic Ries' supplier-customer model**

**Juran reference on design**

<sup>26</sup>Juran includes a chapter in his book on "Designing for Quality - Statistical Aids."

<sup>26</sup> Juran and Gryna, Chapter eight. pp. 203 - 226.

6.2 Design Input

**Design input to be technically correct and complete/** Design inputs should be technically correct and complete. These inputs may include such information as design bases, health and safety considerations, expected life cycle, performance parameters, codes and standards requirements, and reliability requirements. Technical design interfaces should be identified in the input documents and methods should be established for their control.

**Possible design function activities** *Tip: At Los Alamos, technical design criteria are usually established by internal staff. A pre-design review may only be a review of these design criteria to assure that design input can be translated into correct design documents. Such a review should include input from sub-system team leaders for the project . For each program or project, a description of the technical design cycle and a design flow chart are invaluable. Design teams should be organized so this cycle is a natural consequence of the organization's way of "doing designs". The following is an example of design functions one might consider:*

- a. Design
  - (1) Design Origination
  - (2) Design verification
  - (3) Design reviews;
    - (a) Preliminary
    - (b) Final
  - (4) Drawing checks
- b. Approval
  - (1) Design interface
    - (a) Design team
    - (b) Vendors
    - (c) Customers
- c. Document Control
  - c. Document control
    - (1) Drawing document control
    - (2) Archival
    - (3) Distribution
- d. Changes
  - d. Changes
    - (1) Design changes
      - (a) Request
      - (b) Review
      - (c) Check
      - (d) Approval
      - (e) Change documentation

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**Necessity of early design review** *On the Importance of design Rafael Aguayo says, "27Once a product is 15 percent designed, it's too late. Problems are already built in that can't be changed or compensated for anywhere down the line"*

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**Defining design interfaces** Administrative interfaces that include authorities, responsibilities, and lines of communication between the project team members should be defined in sufficient detail to identify and establish relationships of such team members as end-user, stakeholders, responsible design agency, designers, purchasing agents, suppliers, and testers/inspectors.

*Tip: For managers new to using contemporary quality techniques in managing their organizations and processes, defining suppliers and customers, both internal and external, may be difficult. Use of the AT&T customer model, as expanded by the*

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27 Aguayo, p. 119.

*DOE, may be helpful in understanding these interfaces. It may be interesting to note that people and organizations that we interact with may be either suppliers or customers depending on the interaction.*

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### 6.3 Design Process

#### Definition of design process

The design process should translate design input into design output documents that are technically correct and meet the end-user's requirements. Aspects critical to the safety or reliability of the designed system, structure, or component should be identified during the design phase. Design output documents should be usable by other project processes such as: manufacturing, assembly, construction, testing, inspection, maintenance, and decommissioning.

#### As installed design

*Tip: Experience has shown that final design documents are usually correct. However, experience has also shown that design documents, all too often, do not represent the final "As installed" situation. It may be worthwhile to consider as part of the responsibility of fabrication, assembly, or installation teams to update drawings so that they reflect the actual installed condition of the designed system.*

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Computer software used to originate or verify design solutions during the design process should be validated or the status of code validation should be identified and documented prior to use.

#### Definitions: Software Validation and Software Verification

*Tip: Commercial software or software developed at Los Alamos that has a number of users and is accepted need not necessarily be subject to the very expensive tests of validation. Codes that might fall into this category are commercial CAD/CAM software in use in industry or the "Two-Dant" codes used in X-Division.*  
**Software Validation.** The test and evaluation of the completed software to ensure operations specified in numerical models are correctly performed and comply with software requirements.  
**Software Verification.** The process of determining whether or not a computational method is a correct representation of the process or system for which it is intended and meets software requirements of the previous phase.

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#### Verify design

The agency accomplishing the design should verify that design output documents meet design input requirements and that any deviations have been approved and documented.

#### Geometric dimensioning and tolerancing

*Tip: Now that many organizations in the Laboratory are interacting more frequently with outside organizations, both in industry, military, and other government agencies, managers recognize that the standard design documents are completed using Geometric Dimensioning and Tolerancing. Computer Aided Design software can easily accommodate these contemporary design techniques.*

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### 6.4 Design Output

#### Design output documented

The completed design should be recorded in design output documents such as drawings, specifications test/inspection plans, maintenance requirements, and reports. As-built drawings and shop drawings should be maintained after production or construction to show actual configuration. The administrative interface process should clearly indicate responsibilities for design output document activities including as-built mark-up and updating during project construction/production phases, media use and transmission, document control and records management.

#### design interface communication

*Tip: To avoid possible conflicts, the design interface control matrix that establishes the interface between sub-systems is used to promote communication between personnel of various sub-systems. Communication between personnel responsible for various sub-systems should be an ongoing part of the process of design as it proceeds from the establishment of Technical Design Criteria to final design.*

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## 6.5 Design Verification

**Design verification a formal process** Design verification is a formal documented process to establish that the resulting system, structure, or component will be fit for the intended use. Design verification methods include, but are not limited to, technical reviews, peer reviews, alternate calculations, and qualification testing. When appropriate, the verification process may take previous validations of similar designs or on similar features of other designs into account. The design verification process may be used to identify opportunities for improvements in the efficiency, productivity, safety, reliability, or cost of the designed system, structure, or component.

### Final design review

*Tip: Design verification may include building and testing prototypes of subsystems to assure their functionality. A Review Interface Distribution for each design document should be established to assure that all sub-systems are reviewed by the correct technically knowledgeable persons to avoid conflicts in design. A Final Design Review may actually be done in two stages. The initial stage is to reveal any possible design conflicts, which should be minimal. The second should take place after design conflicts are corrected. The second stage of the Final Design Review should certainly be much less involved than the initial.*

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### Design and graded approach

Design verification should be performed by technically knowledgeable persons separate from those who performed the design. Interim verifications may be made at predetermined stages of design development. The extent and number of design verifications should be based on a graded approach and should depend on the designed product's complexity and importance to project success.

### Sub-teams' Design verification

*Tip: Cross check designs by members of other sub-teams who are on the same project or program and who are technically competent to review designs. As mentioned in tab 2, Training and Certification of Personnel, managers should have the authority to decide on the certification of personnel, including reviewer certification.*

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### Timing of design verification

Design verification should be completed before design output is used by other organizations or to support other work such as procurement, manufacture, construction, or experiment. When this timing cannot be achieved, the unverified portion of the design should be identified and controlled. In all cases, design verifications should be completed before relying on the system, structure, or component to perform its function and before installation becomes irreversible.

*Tip: Procurement, suppliers, vendors, fabrication teams, assembly teams, construction teams, installation teams, technical acceptance teams and customers may all be included, as necessary, in design reviews*

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## 6.6 Design Changes

**Design changes** Design changes, including field changes and nonconforming items dispositioned "use-as-is" or "repair," should be controlled by measures commensurate with those applied to the original design. Temporary modifications should receive the same levels of control as the designs of permanent modifications.

### Design change, a formal process

*Tip: Design change control should be a formalized documented process that includes a Change Request. A Change Request should include such information as: number, date, project engineer, or physicist, drawing identification, change description, justification, cost estimate, person responsible for completing the change, approvals, and a drawing control checklist. Approvals should be required by all persons identified by the Design Interface Control Matrix. Nonconforming items that are not rejected and fall into the categories of "use-as-is" or "repair" should be subject to the same rigors of design change.*

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## 6.7 Applicable standards

The following consensus standards provide acceptable methods for implementing many of the requirements of Criterion 6; Although, some of the standards do not fully meet all of the requirements. The principles, recommended approaches, and applications contained in these standards may be used in conjunction with 10 CFR Part 830.120 in the development and implementation of an effective design and design change control system.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.4, "Design Control."
  2. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality System Elements - Guidelines, Section 8, "Quality in Specification and Design."
  3. DOE/RW/0333P, dated December 18, 1992 Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program, Section 3.0, "Design Control," and Supplement I, "Software."
  4. NE F 1-2T, dated January 1, 1989, Preparation of plant and System Design Description Documents.
  5. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Basic Requirement 3, "Design Control," Supplement 3S-1, "Supplementary Requirements for Design Control," and Nonmandatory Appendix 3A-1, "Nonmandatory Guidance on Design Control."  
(See note on NQA-1-1994, page 15.)
  6. ASME NQA-2-1989, Quality Assurance Requirements for Nuclear Facility Applications, Part 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications."  
(See note on NQA-1-1994, page 15.)
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## 6.8 References

1. 10 CFR Part 50, Appendix A, General Design Criteria for Nuclear Power Plants.
2. NUREG 0856 (1983), Final Technical Position on Documentation of Computer Codes for High-Level Waste Management.
3. ANSI/ASQC Standard E4-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.6, "Use of Computer Hardware and Software," and Part C, Section 4.2, "Design of Systems."  
PARTIAL LIST OF ADDITIONAL ORDERS, CODES, AND STANDARDS THAT MAY BE HELPFUL  
*EPA QAMS 540*, Data Quality Objectives for Remedial Response Activities  
*Std 729-1983*, IEEE Standard Glossary of Software Engineering Terminology  
*Std 730-1984*, IEEE Standard for Quality Assurance Plans  
*Std 830-1984*, IEEE Guide to Software Requirements Specifications  
*Std 983-1986*, IEEE Guides to Software Quality Assurance Planning

### LABORATORY ORGANIZATIONAL CONTACTS

Computing and Communications Division (CIC-DO), (505) 667-6164  
Design Group (ENG-3), (505) 667-4296

## CRITERION 7      PROCUREMENT

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### Procurement requirements

- Requirements from 10 CFR Part 830.120, (C), (1), (vii), and DOE Order 5700.6C, criterion 7:
- {1} *Procurement.* The organization shall ensure that procured items and services meet established requirements and perform as specified.
  - {2} Prospective suppliers shall be evaluated and selected on the basis of specified criteria.
  - {3} Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented. (From DOE Order 5700.6C; The organization shall verify that approved suppliers can continue to provide acceptable items and services.)
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### Criterion seven LANL response

- Response from the LANL Quality Assurance Management Plan (QAMP), page 5, section 4.5:
- Procedures will be established to document and control the procurement of quality affecting (including safety) items and services.
  - The requesting organization will use established Laboratory guidance for applying quality assurance controls for procurement.
  - Line management will determine in specifications, drawings, and procurement documents the specification/technical requirements and applicable codes, standards, and necessary QM activities associated with a given procurement.
  - Schedule and acceptance requirements will be established by the requester, including any special handling, packaging, shipping, or storage requirements.
  - Suppliers will be evaluated and selected on the basis of specified criteria. Ongoing reviews to determine suppliers' continued ability to provide acceptable items and services will be performed.
  - Nonconforming items or services will be documented and controlled to preclude use until agreement with the required technical specification/requirements is demonstrated.
  - Deviations from the requester's requirements will be documented, controlled, reviewed, and approved by the requester.
  - Procured items must meet established requirements and perform as specified.
  - Information related to supplier qualification activities and cases of supplier fraud will be conveyed to the DOE in accordance with DOE requirements.
  - Appropriate documents and records will be generated and retained to support the overall procurement action and achievement of the specified requirements.
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## IMPLEMENTATION GUIDANCE

See "NOTE:" at the bottom of page 12 in tabbed section 1.

FROM THE 10 CFR 830.120 "IMPLEMENTATION GUIDE," G-830.120-REV.0

## 7. PROCUREMENT

### 7.1 Introduction

#### Procurement process

The procurement process should ensure that items and/or services provided by suppliers meet the requirements and expectations of the end-user. The procurement process should be planned and controlled to ensure that the end-user's requirements are accurately, completely, and clearly communicated to the supplier; that the suppliers', designers', and end-users' requirements are met during the production phase; and that the proper product is delivered on time and maintained until use.

#### Quality Management at BUS-4

*Tip: The Quality Management Support Group maintains a permanent staff in the Business Operations Division to help with quality concerns with particular emphasis in: materials management (BUS-4), procurement (BUS-5), and property management and packaging and transportation (BUS-6). If the "QA" box is checked on the purchase request, that procurement receives special attention.*

## Procurement by graded approach

The stringency of procurement requirements should be commensurate with the importance of the purchased items or services to the project. Management controls exist for DOE procurements and subcontracts through applicable DOE Orders, Department of Energy Acquisition Regulations (DEARs) in 48 CFR Part 9, and Federal Acquisition Regulations (FARs) in 48 CFR Parts 1 to 99. Criterion 7 of 10 CFR Part 830.120 should not be interpreted to require the development of redundant procurement management systems, but rather to ensure that existing procurement management systems adequately respond to end-user requirements.

## Deming and Juran on procurement

*Tip: The Graded Approach should be used for procurement. At first glance Deming and Juran seem to have a slightly different approach with suppliers or vendors. Deming says to reduce to a single source the number of suppliers for any one given item. He espouses developing a partnership with suppliers to assure that your standard of supplied items meets your requirements. His thesis is that a long-term relationship results in higher quality supplied items.<sup>28</sup>*

*Juran, on the other hand, says to develop multiple sources of suppliers. He further says that you should work with vendors in a partnership to assure that their quality meets your standards. He discusses evaluation of vendors in a variety of topics. He also has an entire chapter on using statistical aids for vendor evaluation.<sup>29</sup>*

*In reality, the Laboratory will probably be successful using ideas from both. Justification for major single-source purchases requires a lot of time and effort.*

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## 7.2 Procurement Documents

### Content

The procurement documents should clearly state test/inspection requirements and acceptance criteria for purchased items and services. Procurement documents should include any specifications, standards and other documents referred to by the design documents. Critical parameters and requirements such as submittals, product related documentation, nonconformance requirements, administrative documentation, personnel or materials qualification, tests, inspections, and reviews should be specified as line items.

### Design process procurement documents

*Tip: A correctly implemented formal design process should include a list of procurement documents required for a given purchase. For more involved purchases, the requester and procurement personnel should work together to complete the procurement package. Even before a vendor is selected, the requester and procurement personnel may work together with a group of vendors to determine procurement document requirements. Those requirements may be modified with cooperation from the selected vendor before contract completion. Modification after contract completion may increase costs.*

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## 7.3 Supplier Qualification

### Supplier periodic evaluation

Required qualified suppliers should be identified early in the design and procurements process. The prospective suppliers should be evaluated to verify their capability to meet performance and schedule requirements. The qualified suppliers should be evaluated periodically to confirm their continuing capabilities.

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<sup>28</sup> Deming, p. 35 - 40.

<sup>29</sup> Juran and Gryna, Chapter nine, pp. 277 - 249, and Chapter ten, pp. 250 - 263.

**Selecting suppliers** Measures for evaluating and selecting suppliers may include:

- a review of the supplier's history for providing identical or similar items or services;
- an assessment of the supplier's capability based on evaluation of its facilities, personnel, and programs; or
- an evaluation of documented qualitative and quantitative information provided by the supplier.

**Supplier Quality Information Group, SQIG**

*Tip: The Laboratory participates in the Supplier Quality Information Group, SQIG . SQIG is a partnership between the various DOE facilities whose purpose is to assure that suppliers for these facilities meet required standards. In addition, SQIG maintains information on vendors who have been formally surveyed by various organizations, and the results of those surveys, whether the vendor was "qualified" or not. DOE has accepted vendor qualification done by one organization and submitted as evidence of the given vendors qualification by another organization. A very important point in qualifying and selecting vendors, particularly for major purchases, is to avoid purchases where the only criterion is low bid. Vendors may be qualified on such parameters as;<sup>30</sup>*

**Selecting suppliers by other than low bid**

*cost  
technical merit  
delivery schedule  
vendor historical record  
vendor quality program  
calibration program  
design capabilities  
other relevant parameters.*

*Each category is assigned a percentage in the order of importance. During a vendor survey, each is scored and the winning vendor chosen according to his or her score. The DOE has accepted purchases by Los Alamos, accomplished in this manner, in a variety of programs.*

**7.4 Supplier monitoring**

Required supplier monitoring should be performed during the procurement process to ensure that acceptable items or services and schedule requirements are being met. Monitoring may include:

- surveillance of work activities;
- inspection of facilities and processes;
- review of plans and progress reports;
- processing of change information; and
- review and disposition of nonconformances.

**Vendor visits**

*Tip: Depending on the importance of the procurement, organizations may visit the vendor at particular "hold points," or choose to temporarily keep on-sight personnel for continually monitoring a vendor's progress . Products may be evaluated even before they are shipped.*

<sup>30</sup> Juran and Gryna, Chapter nine, pp. 277 - 249, and Chapter ten, pp. 250 - 263.

## 7.5 Nonconformance and corrective action

**Nonconformances** Some programs or projects may be required to establish a formalized process to document occurrences when purchased items or services do not meet specifications. This process should specify the roles and responsibilities of program/project participants to ensure that results of actions taken meet program/project requirements.

### LANL Suspect Materials and Counterfeit Fasteners Program

*Tip: The Laboratory has begun a Suspect Materials and Counterfeit Fasteners Program. During the past few years, items and materials whose properties were inferior, or even counterfeit have entered this country. An effort has been underway to identify and properly dispose of these materials and fasteners. Some of the worst problems have been with fasteners, i.e. high-strength screws and bolts that enter the Laboratory on otherwise high-quality components, such as head bolts on compressors. An inspection and acceptance testing program should be established for Laboratory projects as needed.*

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## 7.6 Inspection

The procurement system should include provisions for inspections. Requirements for inspections should be obtained from design documents. Inspections should be adequate to ensure conformance with purchase requirements including verifying that specified documentation has been provided by the supplier. The inspection should verify that items were not damaged during shipment. Inspection may include the following methods:

- inspections of materials or equipment at the supplier's plant;
- receipt inspection of the shipped items;
- review of objective evidence such as certifications and reports; and
- verification of testing of items prior to or following shipment.

The procurement system should include provisions for conducting testing activities that may be required during the procurement process.

### Graded approach

*Tip: Inspections can be costly and should be performed according to the importance of the procurement, or for ES & H purposes. Inspecting to achieve quality should never be done. This is the lesson of all the contemporary authorities on quality. Achieving quality begins at the conceptual stage of product or process development. However, there are situations where 100% acceptable parts or "zero defects" is absolutely necessary. Principles have been developed to minimize the cost of testing.<sup>31</sup>*

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## 7.7 Product documentation

Supplier generated documents should be adapted through the procurement system and controlled and processed by the end-user organization according to the provisions of Criterion 4 (Documents and Records). These documents may include certificates of conformance, drawings, analyses, test reports, maintenance data, nonconformances, corrective actions, approved changes, waivers, and deviations.

*Tip: See Tip, section 7.2.*

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## 7.8 Applicable standards

The following consensus standards provide acceptable methods for implementing many of the requirements of

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<sup>31</sup> Deming, Chapter 15, "Plan for Minimum Average Total Cost for Test of Incoming Materials and Final Product," pp. 407 - 464.

criterion 7, although some of the standards do not fully meet all of the requirements. The principles and recommended approaches and applications contained in these standards may be used in conjunction with 10 CFR 830.120 in the development and implementation of an effective system for procurement management.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.6, "Purchasing," and Section 4.7, "Purchaser Supplied Product."
  2. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality System Elements - Guidelines, Section 9, "Quality in Procurement."
  3. DOE/RW/0333P, dated December 18, 1992 Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program, Section 4.0, "Procurement Document Control,:" and Section 5.0, "Control of Purchased Items and Services."
  4. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Basic Requirements 4, "Procurement Document Control," and 7, "Control of Purchased Items and Services," Supplements 4S-1 and 7S-1, and Appendices 4A-1 and 7A-1. (See note on NQA-1-1994, page 15.)
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## 7.9 References

1. 48 CFR Parts 1 - 99 Federal Acquisitions Regulations System.
2. Electric Power Research Institute Guideline EPRI NP-5652, 1988 Revision, "Guidelines for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications."
3. IAEA Safety Guide 50-SG-QA3, to be issued, Procurement of Items and Services.
4. ANSI/ASQC Standard E4-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.4, "Procurement of Items and Services."

PARTIAL LIST OF ADDITIONAL ORDERS, CODES, AND STANDARDS THAT MAY BE HELPFUL  
*DOE/ER-0133, US-20-A-B & E*, Recommended Practices and Guidelines for Procurement of Magnetic Fusion Energy Electrical Equipment

### LABORATORY ORGANIZATIONAL CONTACT

Procurement (BUS-5), (505) 667-4410

## CRITERION 8 INSPECTION AND ACCEPTANCE TESTING (I&AT)

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### Calibration requirements

Requirements from 10 CFR Part 830.120, (C), (1), (viii), and DOE Order 5700.6C, criterion 8:  
{1} Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criterion. (DOE Order 5700.6C leaves out the word "services.")  
{2} Equipment used for inspections and tests shall be calibrated and maintained.

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### Criterion Eight LANL response

Response from the LANL Quality Assurance Management Plan (QAMP), page 5, section 4.8:

- Procedures will be developed to ensure that inspection and testing requirements are identified and activities are conducted and documented at established hold or witness points.
- This should be done in accordance with criteria derived from approved drawings, specifications, safety analyses, or other technical documents.
- When nonconforming items have been reworked, the reworked items will be inspected for conformance to the original requirements.
- Personnel performing inspections and tests will be trained and qualified in the test procedures and the equipment to be used and will be certified in the appropriate discipline as necessary.
- Measuring and test equipment (M&TE) used as a basis for acceptance or testing will be identified by line and technical management.
- M&TE procedures will provide for the unique identification, maintenance, and calibration of instruments to specified standards, ranges, and tolerances appropriate to their use.
- The specified standards will be traceable to applicable national standards.
- Calibration sources will be qualified by the Laboratory.
- Controlled M&TE will be included within a recall system to ensure the calibration interval is not exceeded.
- Out-of-calibration conditions will be documented and prior use analyzed to evaluate impact on the validity of acquired data and to determine necessary corrective actions.

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## IMPLEMENTATION GUIDANCE

See "NOTE:" at the bottom of page 12 in tabbed section 1.

FROM THE 10 CFR 830.120 "IMPLEMENTATION GUIDE," G-830.120-REV.0

### 8.0 INSPECTION AND ACCEPTANCE TESTING

#### 8.1 Introduction

#### Verifying acceptable conditions

Inspections/tests are accomplished to verify that physical characteristics and functions of systems, structures, and components are acceptable to the organization that will use the systems, structures, and components. Systems, structures, and components requiring inspection/test should be identified early in the design phase.

*Tip: The processes or methods used for inspection and acceptance testing should be specified or developed concurrently with design. "Hold or witness points" should also be specified.*

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<b>Graded approach inspections</b>	<p>Inspections and tests should be conducted according to a graded approach. Acceptance parameters and other requirements such as inspections/tests equipment or qualified inspection/test personnel should be specified in design documentation.</p> <p><i>Tip: The depth and scope of the inspections and the degree of independence of the inspectors should also be based on the risk and complexity of the work.</i></p>
<b>Comment on SSC</b>	<p>Systems, structures, and components should be ready for service at the conclusion of the inspection or test process. The types of systems, structures, and components and the length of time they are to remain in storage should be considered when generating the inspection or test plan.</p>
<b>Shelf life</b>	<p><i>Tip: Shelf life of systems, structures, and components should be considered when they are stored before use. Degradation should be determined to establish the maximum storage time. Therefore, items with a shelf life should be identified with a date tag or some other method that gives an obvious date that the item must be put in service.</i></p>
<b>Failed SSC not used</b>	<p>The inspection/test process should identify the status of systems, structures, and components requiring examination to ensure that failed or untested systems, structures, and components are not used. A method should be developed which controls reinspection and retesting for previously failed systems, structures, and components. The methods should provide for review and documentation of changed inspection/test parameters.</p>
<b>I&amp;AT design change</b>	<p><i>Tip: Since inspection and test parameters are established by design specifications, any change in these parameters should be treated as a design change. See Criterion 6, section 6.2, Design Input and 6.5, Design Verification.</i></p>
<b>I&amp;AT by Qualified personnel</b>	<p>Inspections/tests should be performed by technically qualified personnel that have the freedom of access and communication to report inspection/test results. Final acceptance of systems, structures, and components should be verified and documented by organizations having the final responsibility for the systems, structures, and components.</p>
<b>I&amp;AT coordinated</b>	<p><i>Tip: The organization having final responsibility for the systems, structures, and components should coordinate the acceptance testing with the testing organization. The design organization whose responsibility it is to provide test requirements and acceptance criteria.</i></p>
<b>"Meets or Exceeds" Criteria</b>	<p>All personnel should check items supplied to their work process to ascertain that the items are correct and suitable for use. All personnel should check their process output to verify that it meets or exceeds requirements.</p> <p><i>Tip: Checking to see that items exceed requirements may be quite costly. Exceeding requirements is a nebulous term because one might ask how far an item must exceed requirements. Establishing exceeds limits might be required to determine mean time between failure (MTBF). When many components are used in parallel in a system, the probability of failure of the system is significantly greater than the probability of failure of any one component.</i></p>

## 8.2 Process

<b>Defining I&amp;AT activities</b>	<p>Inspection/test methods should be established that define the requirements for activities that verify conformance of systems, structures, and components with specified requirements. Results of these activities should be documented and retained as project records. Inspection/test activities should be performed by persons other than those who performed or directly supervised the work being examined.</p>
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*Tip: A distinction should be made here. Persons may inspect or test their own work for quality or workmanship. They cannot, however, perform inspections or tests for acceptance.*

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**I&AT performed to written directives**

Inspections/tests should be performed to written directives. Appropriate sections of approved codes or standards may be used for acceptance requirements and inspection/test methods in lieu of specially written test procedures. Inspection/test documentation should contain provisions for at least the following:

- identification of characteristics to be examined;
- required qualifications of individuals who perform the examination;
- a description of the examination methods including equipment and calibration requirements;
- acceptance and rejection criteria;
- required safety measures ; and
- action taken concerning any deviations noted.

*Tip: Additional inclusions might be:*

- <sup>32</sup> Instructions and prerequisites to perform the test;
- completeness and accuracy of the data;
- inspection hold points as required; and,
- test article configuration.

Inspection/test results should be evaluated and verified by authorized personnel to document that all requirements have been satisfied. Records should, at a minimum, identify:

- item tested;
  - date of test;
  - tester or data recorder;
  - observations;
  - results and acceptability; and
  - action taken concerning any deviations noted.
- 

**8.3 Control of Measuring and Test Equipment**

The inspection and acceptance testing methods should establish requirements for a calibration system to ensure that measuring and test equipment (M&TE) used to verify conformance to design requirements are of the proper type, range, accuracy, and are uniquely identified and traceable to their calibration data.

**Calibration of M&TE.**

*Tip: To determine which M&TE requires calibration, use the step-by-step process described in the Calibration Handbook under the heading "Identifying M&TE That Requires Calibration."*

*The instruments to be calibrated, planned calibrator to be used, frequency of calibration, and methods of documentation should be summarized in a calibration plan as described in the Calibration Handbook.*

*Unfortunately, some of the technical staff at Los Alamos have had poor experiences with calibration departments in industry and elsewhere, having had test equipment whisked away to be calibrated according to some predetermined schedule. To avoid this situation at Los Alamos, responsibility for determining which M&TE requires calibration and assuring that calibrations are performed rests with the line management of the organization that owns the equipment, with the calibration organizations providing service upon request.*

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<sup>32</sup> DOE Order 5700.6C, Attachment I, section II, A, 4, B, (4), p. 13.

## Calibration Groups

*The Laboratory provides a wide variety of calibration services, see a listing of Laboratory contacts at the end of this section.* <sup>33</sup>*The Health Physics Measurement group, ESH-4, does radiation instrumentation and calibration. The Calibration Group, ESH-9, is responsible for standards calibration.* <sup>34</sup>*See the Laboratory Handbook on Calibration, QM Reference 8.*

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The method should ensure that adequate procedures for testing, retesting, adjusting, and re-calibration of M&TE are maintained and documented by organizations performing inspection and testing functions. When applicable, M&TE should be calibrated to standards traceable to the National Institute of Standards and Technology.

## Calibration where no standard exists.

*Tip: There may be instances where no national standards exist, particularly in basic research that is at the edge of technology. In such instances, more rigorous attention should be paid to the documentation of the calibration methods used, i.e. if you "invent" your own calibration methods, document them!*

## 8.4 Applicable standards

The following consensus standards provide acceptable methods for implementing many of the requirements of criterion 8, although none of the standards fully meets all of the requirements. The principles and recommended approaches and applications contained in these standards may be used in conjunction with 10 CFR 830.120 in the development of an effective inspection and acceptance program.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.10, "Inspection and Testing," Section 4.11, "Inspection, Measuring, and Test Equipment," and Section 4.12, "Inspection and Test Status."
2. ISO-9002-1987 (ANSI/ASQC Q92-1987), Quality Systems - Model for Quality Assurance in Production and Installation, Section 4.5, "Inspection and Testing," Section 4.6, "Inspection, Measuring, and Test Equipment," and Section 4.7, "Inspection and Test Status."
3. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality System Elements-Guidelines, Section 11.7, "Control of Verification Status," Section 12, "Product Verification," and Section 13, "Control of Measuring and Test Equipment."
4. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Section 10, "Inspection," Section 11, "Test Control," Section 12, "Control of Measuring and Test Equipment," Supplements 10S-1, 11S-1, and 12S-1.
  - NOTE: Supplements 2S-1, 2S-2, and 2S-3; and Nonmandatory Appendices 2A-1 and 2A-3 contain useful capability standards for inspection and test personnel.  
(See note on NQA-1-1994, page 15.)
5. ASME NQA-2-1989, Quality Assurance Requirements for Nuclear Facility Applications, Part 2.16, "Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities."  
(See note on NQA-1-1994, page 15.)
6. MIL-STD-45662A, Calibration System Requirements, June 10, 1980; Revision A, August 1, 1988.

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<sup>33</sup> Group ESH-4, *Health Physics Measurements, FY '95 Management Plan*, Dennis Vasilik, Group Leader, Los Alamos Laboratory, February 1995.

<sup>34</sup> *Calibration Handbook*, " Los Alamos Laboratory publication, LALP-93-47, June 1993

## 8.5 References

1. DOE-ER-STD-6001-92, dated June 1992, Implementation Guide for Quality Assurance Programs for Basic and Applied Research, Page 11.
2. American Society for Nondestructive Testing Standard ASNT-TC-1A.  
  
NOTE: Contains capability standards for NDT/NDE personnel.
3. NUREG 1293, Revision 0, dated January 1989, Quality Assurance Guidance for Low Level Waste Disposal Facility, Section 10, "Inspection," and Section 11, "Test Control."
4. MIL-I-45208A, Inspection System Requirements, December 29, 1960; Revision A, December 16, 1963.
5. IAEA Safety Guide 50-SG-QA-13, to be issued, Inspection and Testing.

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### PARTIAL LIST OF ADDITIONAL ORDERS, CODES, AND STANDARDS THAT MAY BE HELPFUL

*DOE-AL 57XA*, AL Standards and Calibration Program  
*DOE-4330.4A*, Maintenance Management Program  
*MIL-STD-105D*, Sampling Procedures and Tables for Inspection by Attributes  
*LALP-93-047*, Calibration Handbook

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### LABORATORY ORGANIZATIONAL CONTACTS

Calibration Group (ESH-9), (505) 667-4864  
Materials Technology: Metallurgy (MST-6), (505) 667-4365  
Fabrication and Assembly Group (ESA-2), (505) 667-6495  
Mechanical and Electronic Engineering Division (ESA-DO), (505) 667-5974  
Radiation and Instrumentation and Calibration Team, Health Physics Measurement Group (ESH-4), (505) 665-4010

## CRITERION 9 MANAGEMENT ASSESSMENT

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### Management Assessment requirements

Requirements from 10 CFR Part 830.120, (C), (1), (ix), and DOE Order 5700.6C, criterion 9:  
{1} 10 CFR 830.120 criterion 9: Management Assessment. Management shall assess their management processes.  
{2} Problems that hinder the organization from achieving its objectives shall be identified and corrected.

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### Criterion nine LANL response

Response from the LANL Quality Assurance Management Plan (QAMP), page 6, section 4.5:

- Each organization's management is responsible for performing internal assessments of that organization's management processes.
- Organizations will use specific management assessment findings to improve product, service, systems, processes, supplier requirements in order to continuously improve the management assessment process.
- The information acquired during this review and assessment will be combined with other internal and external information to develop a comprehensive perspective on the overall adequacy and effectiveness of the management systems to achieve stated QM objectives.
- Special attention will be given to methods of improving processes and procedures, and the barriers to achieving QM goals and objectives will be identified and addressed.
- The goal of the Laboratory's assessment program is improvement in work products and work processes.

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## IMPLEMENTATION GUIDANCE

See "NOTE:" at the bottom of page 12 in tabbed section 1.

FROM THE 10 CFR 830.120 "IMPLEMENTATION GUIDE," G-830.120-REV.0

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## 9. MANAGEMENT ASSESSMENT

### Differences between the Order and the Rule

*Tip: To have this guide satisfy the requirements of both the Rule and the Order in a strict interpretation, this criterion would have to be treated differently depending on which set of requirements the program was required to uphold. From a practical standpoint, the response given in the Quality Assurance Management Plan satisfies both. Bullet two in the response above is intended to satisfy the requirement to assess the Quality Management Program. Bullet four satisfies the requirement to assess management processes. For a manager to understand his or her management effectiveness it would be logical to want to know both answers. With the help of the ESH-14 assessment section, this is achievable.*

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### Implementation Guidance for the Rule, 10 CFR 830.120

#### 9.1 Introduction

### Manager's assessment responsibility

Managers at every level should periodically assess the performance of their organization to determine how well leadership is being provided to enable the organization to continuously meet the customer's requirements and expectations. This assessment should place emphasis on the use of human and material resources to achieve the organization's goals and objectives. The management assessment should include an introspective evaluation to determine if the entire integrated management system effectively focuses on meeting strategic goals. Criteria set forth in the Presidential Award for Quality, the Malcolm Baldrige National Quality Award, or the Quality Improvement Prototype Award may be used as a basis for management assessments.

**Malcolm Baldrige  
National Quality  
Award**

*Tip:* <sup>35</sup>*The Malcolm Baldrige National Quality Award for excellence and quality achievement in the United States is equivalent to the W. Edwards Deming Award for Quality in Japan. Both awards are equally prestigious in terms of recognizing quality in the private sector. Baldrige was the U.S. Secretary of Commerce from 1981 until his death in 1987. He was a rancher from Mountainaire, New Mexico, so the Award named after him should be particularly interesting to us. The National Institute of Standards and Technology (NIST) manages the Award program and the American Society for Quality Control assists under a contract to NIST. The Baldrige Award was established to stimulate industry to achieve world class Quality. As a side note, the State of New Mexico has awards now based on Baldrige Criteria for New Mexico Organizations.* <sup>36</sup>*Quality New Mexico, recognized as the official state program, is a non profit organization that administers the state award.*

*The core Values and concepts are embodied in seven categories:*

*1.0 Leadership Included in this category is the organization's leadership system, strategic directions, and expectations. Expectations include corporate responsibility and citizenship.*

*2.0 Information and Analysis*

*This category includes requirements for overall performance.*

*3.0 Strategic Planning*

*This category addresses strategic and business planning and deployment of plans with a strong focus on customer and operational performance requirements.*

*4.0 Human Resource Development and Management*

*This category focuses on the human resource practices.*

*5.0 Process Management*

*Effective design, a prevention orientation, evaluation and continuous improvement, linkage to suppliers, and overall high performance are included in this category.*

*6.0 Business Results*

*Superior value of offerings as viewed by customers and the marketplace, and superior company performance reflected in productivity and effectiveness indicators define this category.*

*7.0 Customer Focus and Satisfaction*

*This category focuses on issues of customers and the marketplace. Metrics are important as feedback parameters to understand the appropriateness of priorities and improvement activities.*

*Normally, the assessment activities of the Quality Management Support Group, ESH-14, focus on using the ten criteria of the Rule and the Order. The Baldrige Criteria have been used in assessing the activities of the entire Laboratory. The Laboratory Quality and Planning Program, QP, is responsible for promoting use of the Baldrige Criteria and initiated an assessment of the Laboratory to its criteria. The assessment section of ESH-14 is capable of performing assessments, at the group level, to those criteria.*

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<sup>35</sup> *Malcolm Baldrige National Quality Award, 1995 Award Criteria*, National Institute of Standards and Technology, Gaithersburg, MD, or American Society for Quality Control, Milwaukee, WI.

<sup>36</sup> *1995 Quality New Mexico Business Plan*, Quality New Mexico, Julia K. Gabaldon, president, Albuquerque, NM.

## 9.2 Responsibility

### Direct participation by managers

Managers should retain overall responsibility for management assessments. Direct participation by managers is essential to the success of the process since management is in the position to view the organization as a total system.

*Tip: Without direct involvement in the assessment process there is the possibility that the manager will lose valuable insight to understanding his organization. This does not mean he or she must do the assessment alone but rather be intimately involved in the process of assessing his or her management processes.*

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## 9.3 Process

### Opportunities for improvement

Management assessments should focus on the identification and resolution of both systemic and cultural management issues and problems. Strengths and weaknesses affecting the achievement of organizational objectives should be identified so that meaningful action can be taken to improve quality.

*Tip: It may seem to be a cliché but weaknesses should be viewed as opportunities to improve management techniques.*

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### Processes that should be addressed

Processes being assessed should include strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, and supervisory oversight and support. Effective management assessments should evaluate such conditions as the state of employee knowledge, motivation, and morale. It should also assess the amount of mutual trust and communication among workers as well as the existence of an atmosphere of creativity and improvement. The adequacy of human and material resources also play an important roll.

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### Directly observing work

Direct observation of work is an effective method of management assessment. It provides the assessor with awareness of all interactions at a work location. Other methods of assessment are most effective when combined with work observation. These methods include interviews of workers, reviews of documentation, and conduct of drills or exercises.

*Tip: Observation of personnel performing their work must be done with great sensitivity. If the worker views observation of his or her work as a test or formal evaluation, the results may be erroneous. "Time-in-Motion" studies have been done for a huge variety of industrial processes. Some companies use results of these studies on which to base their fees. For instance one could research manuals for how long it takes to change a given part on an automobile. In the research and development environment of Los Alamos this method should be established as credible as well as acceptable before it is used as an assessment tool.*

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## 9.4 Results

### Continuous improvement from results

Management assessment results should be used as input to the organization's continuous improvement process.

*Tip: The uniqueness of Los Alamos should make it a place where management, traditionally shunned by physicists and engineers, has the opportunity to try new and innovative management processes. Given the view by DOE that all work can be planned, performed and assessed, this should provide a challenge to improve morale, cut R & D costs and still produce high quality products of science.*

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9.5 Applicable standards

The following consensus standards provide acceptable methods for implementing many of the requirements of Criterion 4. Note that no single standard may fully meet all of the requirements. The principles and recommended approaches and applications contained in these standards may be used in conjunction with 10 CFR Part 830.120 in the development of an effective management assessment program.

- 1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.17, "Internal Quality Audits."
- 2. DOE-ER-STD-6001-92, dated June 1992, Implementation Guide for Quality Assurance Programs for Basic and Applied Research, Part II. C, Criterion 9, "Management Assessment."

9.6 References

- 1. DOE Student Training Manual, dated February 10, 1993, Management Assessment Training.
- 2. ASQC Energy Division, Quality Surveillance Guidelines and Quality Surveillance Handbook, ASQC Quality Press, 1992.
- 3. NUREG/CR-5151, dated February 1989, Performance-Based Inspections.
- 4. DOE/EH-135, dated June 1990, performance Objectives and Criteria for Technical Safety Appraisals at Department of Energy Facilities and Sites.
- 5. Presidential Award for Quality, Federal Quality Institute.
- 6. Quality Improvement Prototype Award, Federal Quality Institute.
- 7. Malcolm Baldrige Award, National Institute for Standards and Technology.
- 8. IAEA Safety Guide 50-SG-QA10, to be issued, Assessment.
- 9. ANSI/ASQC E4-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.9, "Quality Assessment and Response."

PARTIAL LIST OF ADDITIONAL ORDERS, CODES, AND STANDARDS THAT MAY BE HELPFUL

DOE 5481.1B, Safety Analysis and Review System  
DOE-AL 54XA, Operational Readiness Review (ORR) Program  
DOE 5480.23, Safety Analysis Reporting

Implementation Guidance for the Order, 5700.6C, Criterion 9

DOE Order 5700.6C requirement

a. Planned and periodic management assessments should be established and implemented as a way to improve quality. Management assessments should focus on how well the integrated quality assurance program is working and should identify management problems that hinder the organization from achieving its objectives in accordance with quality, safety, and environmental requirements.

Focus on improvement

Tip: Management assessments review the organization's management ability, techniques and plans. Such internal assessments may assist management in identifying QM

*deficiencies. Effective management assessments focus attention on improving management itself. They focus on the management processes rather than on personnel behaviors.*

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**Senior management to retain responsibility**

b. Senior management should retain overall responsibility for management assessments. Direct participation by senior management during management assessments is essential. This process should involve all levels of management, as appropriate.

*Tip: As the responsibility of senior management, management assessments reflect management's interest in and support of management process activities. Senior management's involvement in the assessment process indicates to line management a high level of commitment not only to improving management itself but to the quality initiative. The QM Program Plan should specify senior management's role in the assessment process.*

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**Assessments should be documented**

c. Management assessment results should be documented. Senior management should take prompt action and document resulting decisions in response to recommendations resulting from the management assessment process. Follow-up should include an evaluation of the effectiveness of management's actions.

*Tip: The emphasis of this criterion should be self improvement of management. When management processes improve the whole organization benefits.*

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**LABORATORY ORGANIZATIONAL CONTACT**

Assessment Section, Quality Management Support Group (ESH-14), (505) 665-5437

## CRITERION 10 INDEPENDENT ASSESSMENT

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### Independent Assessment requirements

Requirements from 10 CFR Part 830.120, (C), (1), (x), and DOE Order 5700.6C, criterion 2:

- {1} *Independent Assessment.* Independent assessments shall be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (From DOE Order 5700.6C; Planned and periodic independent assessments shall be conducted to measure item quality and process effectiveness and to promote improvement.)
  - {2} The group performing independent assessments shall have sufficient authority and freedom from the line to carry out its responsibilities. (From DOE Order 5700.6C; The organization performing independent assessments shall have sufficient authority and freedom from the line organization to carry out its responsibilities.)
  - {3} Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed. (From DOE Order 5700.6C;
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### Criterion Ten LANL response

Response from the LANL Quality Assurance Management Plan (QAMP), page 7, section 4.5:

- The independent assessment is a function of the Audits and Assessments Office (AA). AA is part of the Director's Office and, therefore, is independent of assessed organizations, facilities, and programs.
  - AA will perform both compliance- and performance-based assessments. Customer expectations, as defined in DOE and Laboratory requirements, will be used as a basis for assessments of organizations, facilities, and environment, safety, and health; quality assurance; maintenance; and safeguards and security programs. Customers may include DOE and Laboratory management, and the assessed organization.
  - AA assessments will be performed by teams whose members will be independent of the organizations, facilities, and programs they evaluate. In addition, they will be subject matter experts, and trained in assessment techniques. Assessment techniques will include operational reviews (walk-downs), interviews with management and employees, and document reviews.
  - A long-range schedule for independent assessments will be developed and routinely updated. Frequency of assessments will be dependent on DOE and Laboratory requirements, inherent risk, public sensitivity, accident experience, and lack of current information about an organization, facility, or program. Performance objectives and criteria, developed from applicable requirements, will be used in the planning and assessments.
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### Assessment responsibilities

- The assessment responsibilities include the following:
  - 1. Identify significant potential problems and noncompliances.
  - 2. Identify the probable causal factor.
  - 3. Document the results.
  - 4. Make suggestions for improvement.
  - 5. Track results.
  - 6. Verify resolution of problems and noncompliances.

### Assessments documented

- Assessment results will be documented in reports that are distributed to the deputy director of the Laboratory and all affected organizations.
  - This information can then be used by Laboratory management for planning and continuous improvement of processes and functions.
  - Reports will include noteworthy practices, findings, causal factors, recommendations, and observations.
  - Findings will be tracked, and corrective actions will be evaluated for adequacy and verified. Lessons learned will be communicated to other organizations.
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IMPLEMENTATION  
GUIDANCE

See "NOTE:" at the bottom of page 12 in tabbed section 1.

FROM THE 10 CFR 830.120 "IMPLEMENTATION GUIDE," G-830.120-REV.0

10 INDEPENDENT ASSESSMENT

10.1 Introduction

**Assessment method established** Management should establish and implement a method for independent assessment of organizations, programs and projects in order to evaluate the performance of work processes with regard to requirements and expectations of customers and toward achieving the mission and goals of the organization. The process should use a performance-based approach with emphasis on results and with implementation status viewed as the baseline. Assessments should be conducted on activities that most directly relate to final objectives and should emphasize safety, reliability, and product performance. Independent assessments may include such methods as inspections, peer and technical reviews, audits, surveillances, or combinations thereof.

**Assessments for discovering problems**

*Tip: Management or internal assessments may identify only a small fraction of the problems that hinder the achievement of quality—often because employees see problems as personal failures and are reluctant to call the attention of their supervisors to process shortcomings. Independent assessments, however, are effective in identifying most of the problems—probably because employees may be willing to tell outsiders what they know when they are sure that their anonymity is protected. In any case, once problems are identified, management can take steps for corrective action. The independent assessment process should be adequately and appropriately documented and implemented in the QM Program Plan because it has significant impact on an organization's ability to achieve and improve quality.*

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10.2 Performing Organization

**Assessment organization independence** The assessing organization should advise management and should report to a sufficiently high level in the overall organization to ensure organizational independence and access to appropriate levels of authority. Personnel performing independent assessments should have the necessary technical knowledge to accurately observe and evaluate activities being assessed. Personnel performing assessments should not have direct responsibilities in the areas they are assessing and should consider the organizations being assessed as customers for feedback concerning observations of performance.

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**Proper assessment environment**

*Tip: Hopefully, with the contemporary quality environment within organizations both in industry and the DOE, the independent assessment, previously referred to as audits, can be a positive experience from which some very favorable "lessons learned" may be gained. If the assessing organization delivers a timely and complete (assessment audit) plan, you may feel that an antagonistic relationship is **not** developing. An audit plan usually consists of the following:*

- *scope*
- *requirements*
- *audit personnel*
- *activities to be audited*
- *organizations to be notified*
- *applicable documents*
- *schedule*
- *written procedures*
- *broad scope checklist*

<sup>37</sup>This checklist is from NQA-1, 1994 Edition.

<sup>37</sup> *Quality Assurance Requirements for Nuclear Facility Applications*, ASME - NQA - 1 - 1994 Edition, Basic Requirement 18, *Audits*, Supplement 18S-1, p. 50.

*Phone calls to the assessment team leader may confirm this. If, from these interactions, you feel fairly sure that this is the case, there is an excellent chance that your organization stands to gain insight to itself that may not otherwise have been possible. Even with some major findings, the assessing organization may try to help you resolve them before the assessment exit meeting. If, in advance, you know that your staff may attend all assessment team meetings, you have a good indication that this will not be a confrontational assessment. Still, prepare for the assessment by studying their assessment plan. Anticipating what information may be required will make the assessment go more smoothly, be completed sooner, and be less disruptive to work being done. The best way to prepare an organization for an independent assessment is to request an assessment by an organization external to your own, unless you have personnel with assessment experience, like the assessment section of the Quality Management Support Group. Try to have an assessment that achieves meeting the requirements of criterion nine for both the Rule, and the Order simultaneously. You may only be required to meet the requirements of one or the other. Having a complete assessment will give you more information about yourself.*

---

#### **Assessment characteristics**

**Tip:** **ASSESSMENT CHARACTERISTICS**  
*There are four types: Findings, Concerns, Observations, and Noteworthy practices. See the glossary to the Guidebook for definitions, QM Reference 9.*

#### **Improper assessment environment**

**Tip:** *Any Quality Manager, who has been through an assessment whose stage is set by adversarial confrontation, may have a hard time accepting the concept of independent assessment being a learning tool for the organization, as described above. Assessors (auditors) who are looking for "I gotchas" still exist, and can be prepared for by educating the organizational staff ahead of time. If that is suspected in advance (a very vague audit plan not delivered on a timely basis is a good indication) the following points may help:*

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#### **Assessment preparation**

- *It is even more imperative to do a self-assessment ahead of time, if a hostile assessment is suspected. If you know your weaknesses ahead of time you can prepare responses to them.*
- *After doing a self assessment, begin corrective action on findings , i.e. have plans written or, if possible, complete corrective action, and document.*
- *Even though you suspect a hostile assessment, present your Pre-assessment at the opening meetings. The assessors may list your findings in their report, but it will lessen the impact since you also have discovered the problems and have initiated corrective action plans.*
- *Cooperate with the assessors without antagonizing them.*
- *Give no more information than requested.*
- *Assign a technically knowledgeable person to each assessor, who realizes that the interaction should be very professional, but not overly friendly. The "I Gotcha" guys are looking for strings to pull.*
- *Do not let any assessor wander freely about your facility.*
- *Be aware of grounds for declaring an assessment invalid, such as a contractor who is doing the assessment having just lost his contract.*

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#### **The opening meeting**

- *At the opening meeting, you will want to discuss the mission and goals of your organization, and answer any questions the assessment team might have. Have team leaders or subject matter experts present, if necessary.*

- *At the opening meeting, clarify any misunderstandings about the assessment plan. If what you received as a plan is vague, try to establish as much detail as possible.*
- 

## **The assessment**

- *Ahead of time, make sure that all of the staff, because any one person may be questioned by the assessor, are instructed to answer questions without offering extra information. If personnel do not know the answer, a simple "I do not know" with no explanation of why the answer is not known, is all that is required. Remember your technical expert "guide" provides a witness to the questioning.*
  - *Your technical expert "guide" should be able to keep the questioning from becoming an interrogation.*
  - *During the assessment, the assessor will probably want to talk to members of the staff for clarification of "objective evidence" that is presented. The assessor may question the way procedures are written and the methods used to accomplish certain tasks. If you can show that procedures or methods work for your organization, that should be the end of the discussion. If the assessor wants to make changes in workable procedures, ask if he is assuming responsibility for those changes. Point out that he cannot.*
  - *If the assessor suggests that additional tasks need to be accomplished (ones that you have a reasonable argument for not doing) ask if the organization he represents is willing to provide the funds for those tasks. Usually, he will decline.*
  - *It is typical for assessment teams to have a meeting at the end of each day to discuss the day's findings. Consider private meetings for your staff, whether or not you're allowed to attend their daily meetings.*
- 

## **The exit meeting**

- *Have someone who is skilled in taking meeting notes present at the exit meeting, preferably a secretary who is accomplished at shorthand.*
  - *In the exit meeting, try to carefully understand all findings. and informally document them. If you can correct a finding before the assessment team leaves, document the corrective action and have it signed by the lead assessor, and the responsible organizational manager.*
  - *The "I Gotcha" assessor's (auditor's) objective is to obtain as many findings as possible. Try to limit findings by pointing out that findings should be categorized, and that one category is one finding. For example, you may not have completed all of your work process procedures and have to complete, say, five procedures. That is not five findings, it is one finding, "All of your work process procedures have not been completed." A list of the uncompleted procedures may be included by the assessor in this one finding.*
  - *You might successfully argue that the assessors list your findings from your "self-assessment" only as observations or concerns, depending on the severity of the finding because you are aware of them, and have begun corrective action. This assumes that you have started those corrective actions.*
  - *At exit, you may argue that your pre-assessment, even though you have findings, is a noteworthy practice.*
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## **Post exit meeting**

- *Have a meeting subsequent to the assessment exit meeting as soon after the assessment as possible to discuss results of the assessment. In spite of ill feelings that might be generated by such a hypothetical assessment,*

nevertheless try to gain "lessons learned" from the experience. This might be the beginning of preparation for the next assessment.

- Start on corrective actions immediately after the assessment.
  - Be demanding about receipt of the assessment report. This is usually required in 30 days, but may be as much as 45 days.
  - Respond to the assessment report as soon as possible after all corrective actions have been completed. Submit "objective evidence" with your corrective action report, if possible. You do not want an uninvited visit by another hostile assessment team sooner than necessary.
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#### **Follow-up assessment**

- The assessing organization may schedule a follow-up assessment that only focuses on those nonconformances that were found at the main assessment.
  - What you are trying to show is that you, as managers, understand your problems and are making an effort to correct nonconformances.
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### **10.3 Process**

**Type and frequency based on a graded approach** The types and frequencies of independent assessments should be based on the status, complexity, and importance of the activities or processes being assessed. The criteria used for assessments should describe acceptable work performance and should promote improvement of the process or activity. Assessments should also address management processes that affect work performance such as planning, program support, and training.

*Tip:* The scope of the assessment should be given in the assessment plan from the assessing organization. There should be enough detail so that your organization may prepare enough "objective evidence" to satisfy the assessors' requests. Again, there are two ways of approaching this situation depending on how antagonistic you suspect the assessment may be.

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#### **Assessor's responsibility**

Personnel performing assessments should focus on improving output quality and process effectiveness by emphasizing continuous improvement methods. Assessment personnel should not reinterpret or redefine the requirements specified in approved programs. The assessors' responsibilities include:

- evaluating work performance and process effectiveness;
- identifying abnormal performance and potential problems;
- finding opportunities for improvements;
- documenting and reporting results; and
- verifying satisfactory resolutions of reported problems.

*Tip:* As a manager whose organization is being audited, it is in part your responsibility to keep the assessment team focused on improvement. Don't just leave it up to your quality advisor, whether he or she is internal or not. Bear the responsibility of representing your organization during independent assessments.

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#### **Adequacy of corrective actions**

The independent assessment process should include verification of the adequacy of corrective actions, including actions identified to prevent recurrence or to otherwise improve performance.

*Tip:* If possible, discuss corrective actions during the assessment meeting. Determine acceptable response so that misunderstandings are avoided. Document the proposed corrective actions and have both the assessment team leader and responsible organizational manager sign them.

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## 10.4 Results

Assessment results should be documented, presented to the organization that was assessed, and provided to the appropriate levels of management for review. Strengths and weaknesses affecting the quality of process outputs should be identified so that meaningful action can be taken to improve quality.

*Tip: Issuance of the formal assessment report is usually required within 30 to 45 days. Hold the assessment team to required schedules, if possible. Make sure, as well, that your response to the assessment report is timely.*

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### Result should improve performance

Independent assessments that verify good performance in some or all areas of an organization may result in a reduction in the frequency and depth of future assessments. Areas of poor or questionable performance should receive increased attention.

*Tip: This is the reason for exemplary performance in an assessment. It takes preparation, even when the assessment environment is friendly.*

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### Lessons learned should be shared

Lessons learned from the assessment process should be communicated to other organizations with similar activities or concerns. Identified action items should be tracked for resolution and evaluated to determine whether similar deficiencies exist elsewhere.

*Tip: The Quality Management Support Group would like to keep copies of each independent assessment if the group performed a requested assessment in preparation for the independent assessment. The reports are considered confidential and are not shared with requesters other than those of the assessed organization. However, if the information in the report is not sensitive, please share your lessons learned.*

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## 10.5 Applicable standards

The following consensus standards provide methods for implementing many of the requirements of Criterion 10. No single standard fully meets all of the requirements. The principles and recommended approaches and applications contained in these standards may be used in conjunction with 10 CFR Part 830.120 in the development of an effective independent assessment program.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.17, "Internal Quality Audits."
  2. DOE/RW/0333P, dated December 18, 1992 Quality Assurance Requirements and Description, Section 18.0, "Audits."
  3. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Section 18, "Audits," Supplement 18S-1, "Supplementary Requirements for Audits," and Appendix 18A-1, "Nonmandatory Guidance on Audits."  
(See note on NQA-1-1994, page 15.)
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## 10.6 References

1. ASQC Energy Division, Quality Surveillance Guidelines and Quality Surveillance Handbook, ASQC Quality Press, 1992.
2. NUREG/CR-5151, dated February 1989, Performance-Based Inspections.
3. DOE/EH-135, dated June 1990, Performance Objectives and Criteria for Technical Safety Appraisals at Department of Energy Facilities and Sites.

4. IAEA Safety Guide 50-SG-QA10, to be issued, Assessment.
5. ANSI/ASQC E4-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.9, "Quality Assessment and Response."

PARTIAL LIST OF ADDITIONAL ORDERS, CODES, AND STANDARDS THAT MAY BE HELPFUL

*DOE 5481.1B*, Safety Analysis and Review System

*DOE-AL 54XA*, Operational Readiness Review (ORR) Program

*US. DOE*, Self-Assessment Guidance Document (available from the Audits and Assessments Office, AA)

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